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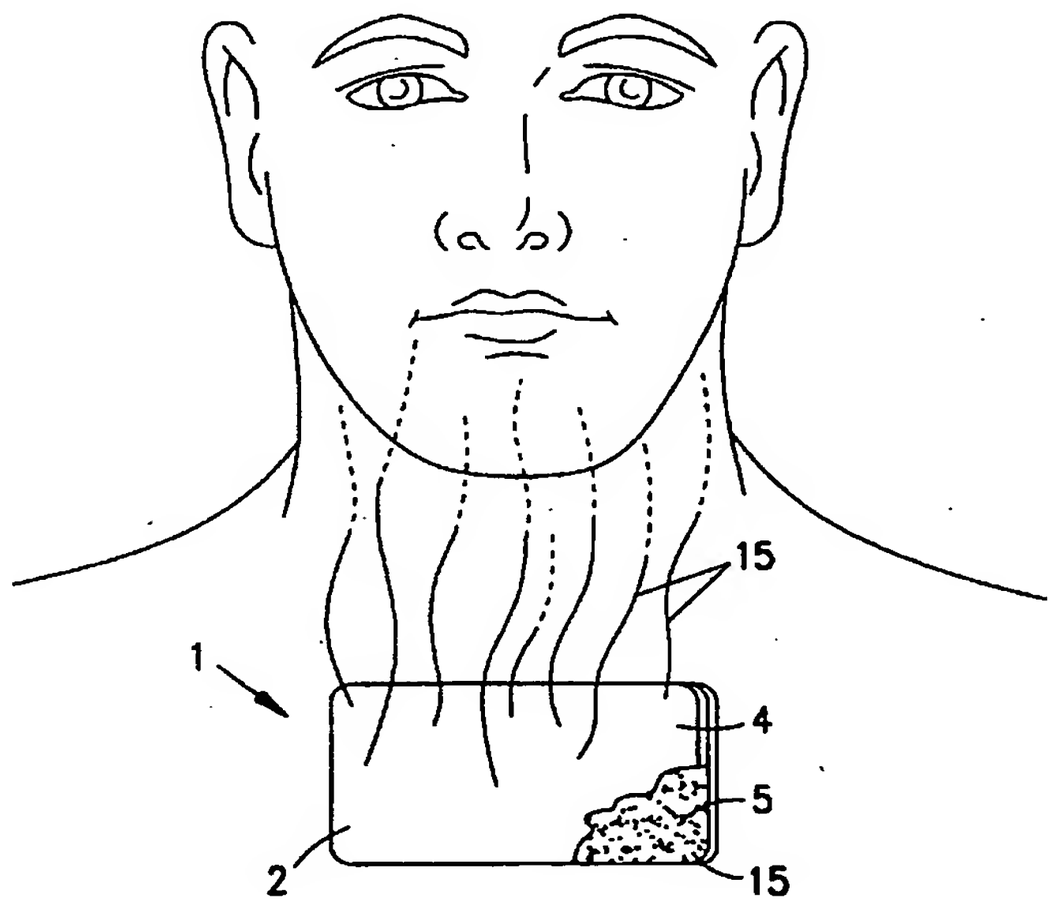
(54) Title: THERAPEUTIC PATCH CONTAINING A LIQUID OR GEL ORGANIC COMPOUND AS A CARRIER



(57) Abstract: A vapor permeable adhesive patch is provided wherein the patch includes a porous backing having a front side and a back side. The patch also includes a therapeutic formulation located on the front side of the backing. The backing includes a flexible sheet of water insoluble porous material. The therapeutic formulation includes a combination of a medicament useful for relieving coughing, a liquid or gel-like, cosmetically acceptable organic compound to act as a carrier for the medicament and at least partially masks the odor of the medicament, and a pressure sensitive adhesive. The liquid or gel-like, cosmetically acceptable organic compound can be a fragrance.

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THERAPEUTIC PATCH CONTAINING A LIQUID OR GEL ORGANIC COMPOUND AS A CARRIER

Background of the Invention

Several patch devices have been used for applying medication to the skin. For example, U.S. Patent No. 4,675,009; U.S. Patent No. 5,536,263; and U.S. Patent No. 5,741,510 each describe a drug dispensing device for the delivery of medication to the skin. While the patches disclosed are generally effective in the delivery of a medicament (e.g., topical antitussive) to the skin, there exists a need for additional non-occlusive (i.e., breathable or vapor permeable), protective, adhesive patches that adhere to FDA regulations.

FDA regulations (e.g., Federal Register, Vol. 48, No. 27, § 341) regulate what components (i.e., "active ingredients"), in a specified amount, may be described as a cough reliever (i.e., topical antitussive). In order to follow FDA regulations, therefore, only a select number of active ingredients that are able to relieve coughing, in a specified amount, may be included in an adhesive patch when the patch is described as a cough reliever (i.e., contains an antitussive). Consequently, it is difficult to manufacture an adhesive patch that includes a topical antitussive, while at the same time maintaining (a) the solubility and stability of the active ingredients in the therapeutic formulation, (b) the pressure sensitive adhesive properties of the therapeutic formulation, and (c) following FDA regulations.

Several commercially available topical cough formulations (e.g., Vicks Vapor Rub®) include one or more components (e.g., camphor and menthol) that are recognized by the FDA as topical antitussives. These formulations, which are advertised as decongestants, include turpentine, which is flammable (i.e., the presence of turpentine in the formulation results in a premix mixture that has a flash point below 140°F). As such, these cough formulations, upon being discarded, can be considered hazardous waste.

Another drawback with the use of turpentine in the topical cough formulation is the unpleasant odor and topical irritant character of turpentine.

Children have shown a heightened dislike for the medicine-like odor and irritating quality of turpentine. See, e.g., Federal Register, Vol. 48, No. 27, § 348.12(a)(4).

One transdermal patch, TheraPatch® Vapor, includes camphor, menthol, adhesives, aloe vera, eucalyptus oil, glycerin, karaya, water and turpentine spirits. The oil premix for TheraPatch® Vapor has a flash point of 114°F, and when this liquid is discarded, it is considered hazardous waste. The flash point of the TheraPatch® Vapor patch was determined to be 140°C. This temperature is just above the cut off for liquids (i.e., the 140°C). However, there is no hazardous waste definition for solids based on the flash point of the solid. As such, the TheraPatch® Vapor, upon being discarded, can be considered as non hazardous waste. However, like the above mentioned topical cough formulations (e.g., Vicks Vapor Rub®), the transdermal patch includes turpentine, which is not preferable for many children.

Accordingly, there is a need for a vapor permeable (i.e., breathable), protective, adhesive patch that can be topically applied, that can relieve coughing, and that is free of components (e.g., turpentine) that contain an unpleasant odor. In addition, there is a need for an adhesive patch that can at least partially mask the unpleasant odor of antitussive medicinals such as camphor, menthol, eucalyptus oil, turpentine oil, thymol, or a combination thereof. The needs also include the solubility and stability of the medicament (e.g., topical antitussive) during the manufacturing, packaging, shipping, and storage of the patch, and the need to maintain the pressure sensitive adhesive properties of the therapeutic formulation. In addition, there is a need to follow FDA regulations (e.g., Federal Register, Vol. 48, No. 27, § 341) for formulations including a topical antitussive.

Summary of the Invention

The present invention provides for a vapor permeable adhesive patch. The patch includes a porous backing having a front side and a back side. The patch also includes a therapeutic formulation located on the front side of the backing. The backing includes a flexible sheet of water insoluble porous material. The therapeutic formulation includes a combination of a medicament,

useful for relieving coughing; a liquid or gel-like, cosmetically acceptable organic compound to act as a carrier for the medicament and at least partially masks the odor of the medicament; and a pressure sensitive adhesive. Preferably, the liquid or gel-like, cosmetically acceptable organic compound is a fragrance. Preferably, the patch can be used to alleviate and/or relieve coughing in a mammal (e.g., human).

Brief Description of the Drawings

Figure 1 illustrates the front side of an adhesive patch.

Figure 2 illustrates the back side of an adhesive patch.

Figure 3 illustrates the front side of an adhesive patch with a backing liner attached to the patch.

Figure 4 illustrates the back side of an adhesive patch with a backing liner attached to the patch.

Figure 5 illustrates the back side of an adhesive patch with a backing liner attached to the patch, wherein the patch is partially detached from the backing liner.

Figure 6 illustrates the back side of an adhesive patch with a backing liner attached to the patch, wherein the patch is partially detached from the backing liner.

Figure 7 illustrates a top view of a specific patch of the present invention.

Figure 8 illustrates a side view of a specific patch of the present invention.

Figure 9 illustrates a specific patch of the present invention in use on the chest.

Figure 10 illustrates a specific patch of the present invention in use between the upper lip and the nose.

Figure 11 illustrates a specific patch of the present invention in use on the throat.

Figure 12 illustrates a specific patch of the present invention in use on the chin.

Detailed Description of the Invention

The vapor permeable adhesive patch of the present invention contains a known, effective and stable amount of topical antitussive. The vapor permeable adhesive patch does not include turpentine, or any other component that has an unpleasant odor. The vapor permeable adhesive patch, therefore, is safe, effective, and convenient for alleviating and/or relieving coughing.

The present invention provides a vapor permeable, adhesive patch that contains a medicament. The medicament is present in the therapeutic formulation, which is present on and in at least a portion of the front side of the backing. The medicament is useful for relieving coughing. It has been surprisingly discovered that an adhesive patch can be manufactured wherein the adhesive patch maintains the desired pressure sensitive adhesive properties, retains the stability and solubility of the medicament in the therapeutic formulation, and is free of turpentine; wherein a liquid or gel, cosmetically acceptable organic compound is used as a carrier for the medicament and other ingredients of the therapeutic formulation. Typically, the liquid or gel compound is a fragrance acceptable for cosmetic use and preferably acceptable for incidental ingestion or absorption into the human body.

The liquid or gel cosmetically acceptable organic compound will preferably have low to moderate volatility as measured by its ability to generate odor. The volatility will not be so high as to significantly decrease the concentration of the liquid organic compound over the life of the patch. The volatility will, however, be high enough such that when desirable, the odor or scent can be detected by the patient. Preferably, the therapeutic formulation **5** of the adhesive patch **1** will emit an odor or scent that is detected by the patient for a period of at least about 10 hours, at least about 8 hours, or at least about 6 hours.

Preferably, the liquid gel cosmetically acceptable organic compound is an ester, terpene, alcohol, ketone, aldehyde, fatty acid, partially or fully esterified fatty acid wherein the structures are cyclic, alicyclic or aromatic, as well as organic compounds having combinations of these functional groups. Hereinafter, the liquid or gel, cosmetically acceptable organic compound will be termed a liquid or gel compound.

Referring to Figs. 1-8, a vapor permeable, adhesive patch **1** of the present invention is provided. The patch **1** includes a backing **2** and a therapeutic formulation **5**. The backing **2** is defined by a front side **3** (the side exposed to the skin during use) and a back side **4** (the side exposed to the environment during use). The backing **2** includes a flexible porous sheet of water insoluble material that provides support for the patch **1**. The backing **2** should be nonirritating to human skin. The backing **2** can be porous since porosity provides openings for receiving the therapeutic formulation **5** and it helps to assure that the patch **1** is vapor permeable. The backing **2** can optionally be woven or non woven. Suitable backings **2** and methods for manufacturing the suitable backings are disclosed in U.S. Patent No. 4,675,009; U.S. Patent No. 5,536,263; U.S. Patent No. 4,696,854; U.S. Patent No. 5,741,510, and references cited therein. The backing **2** can be manufactured from any suitable material, provided the suitable material can form a flexible, bendable, pliable, and/or stretchable sheet of water insoluble porous material.

As shown in Figs. 1-6, the backing **2** includes a front side **3** and a back side **4**. The patch **1** includes a therapeutic formulation **5** located on and in the front side **3** of the backing **2**, wherein the therapeutic formulation **5** includes a combination of a medicament **15** useful for relieving coughing; a pressure sensitive adhesive and a liquid or gel compound that dissolves the medicament **15**. Preferably, the liquid or gel compound at least partially masks the unpleasant odor of the medicament **15** if such odor is present. The therapeutic formulation is located on at least a portion of the front side **3** of the backing **2**.

Preferably, the patch **1**, upon contact with skin, will allow the skin to breathe. More preferably, the patch **1**, upon prolonged contact with skin, will hold in place the therapeutic formulation **5** and allow the skin to breathe over prolonged periods of time, such as up to about 10 days, up to about 1 day, or up to about 8 hours.

The backing **2** is a porous, self-supporting sheet of water insoluble, polymeric or natural material that provides strength and integrity for the therapeutic formulation **5**. For example, the backing **2** can be water insoluble polymeric fibers, open cell foam backing (e.g., polyurethane, polyvinyl chloride, or polyethylene), a porous film or any other kind of matrix with spaces within

the matrix. Preferably, the backing **2** can be polyester, polyurethane, polyolefin, polyamide fibers, natural fibers, cotton fibers, polycellulose fibers, or any mixture thereof.

A specific backing **2** is a lightweight, porous, pliable strip composed of a nonwoven fabric of polymeric or natural fibers such as polyester, cotton or cellulose fibers bonded together with a sizing resin. Additional stable, water insoluble flexible sheet materials are disclosed in U.S. Patent No. 4,675,009; U.S. Patent No. 5,536,263; U.S. Patent No. 4,696,854; U.S. Patent No. 5,741,510, and references cited therein, and are suitable as backings according to the present invention. The infusion of the therapeutic formulation **5** into the backing **2** is accomplished with the use of a continuous process mixer, as disclosed in U.S. Patent No. 5,536,263, and references cited therein.

As shown in Figs. 3-6, the patch **1** is preferably reversibly attached to a backing liner **10**. The backing liner **10** helps to maintain the adhesiveness of the patch **1** prior to use, such as during manufacturing, packaging, shipping, and/or storage. Any suitable backing liner can be employed for use in the present invention. Suitable backing liners **10** are readily known to those of skill in the art. See, U.S. Patent No. 4,675,009; U.S. Patent No. 5,536,263; U.S. Patent No. 4,696,854; U.S. Patent No. 5,741,510, and references cited therein for further descriptions of backing liners useful in the present invention. The backing liner **10** can include a perforation **12** that allows the tab section **11** of the backing liner **10** to be removed (see, Figs. 5-6). Removal of the tab section **11** of the backing liner **10** allows the patch **1** to be removed from the backing liner **10** with relative ease.

The therapeutic formulation **5** includes a combination of a pressure sensitive adhesive and a medicament **15** useful for relieving coughing, and a liquid or gel compound that dissolves the medicament **15**. As used herein, the medicament can be a topical antitussive, as disclosed in Federal Register, Vol. 48, No. 27, § 341.3(c) and § 341.14(b), and references cited therein; or Handbook of Nonprescription Drugs, 10th Edition, 1993. The topical antitussive can effectively suppress coughing as disclosed in Federal Register, Vol. 48, No. 27, § 341.74, and references cited therein. Suitable topical antitussives include camphor, menthol, eucalyptus oil, turpentine oil, thymol, or a combination

thereof. Preferred topical antitussives include camphor, menthol, or a combination thereof.

The medicament **15** can be present in any appropriate and suitable amount. Preferably, the medicament **15** can be present in about 0.01 wt.% to about 99.9 wt.% of the therapeutic formulation **5**. More preferably, the amount of medicament **15** present in the therapeutic formulation **5** can depend upon the specific compound or compounds employed as the medicament **15**. For example, camphor can be present up to about 99.9 wt.% of the therapeutic formulation **5** and menthol can be present up to about 99.9 wt.% of the therapeutic formulation **5**.

Preferably, the amount of medicament **15** present in the therapeutic formulation **5** follows FDA regulations, Federal Register, Vol. 48, No. 27, § 341 or complies with Handbook of Nonprescription Drugs, 10th Edition, 1993, p. 108. While the amount of medicament **15** present in the therapeutic formulation **5** can comply with FDA regulations (e.g., Federal Register, Vol. 48, No. 27, § 341), it is appreciated that those of skill in the art understand that the amount of camphor and/or menthol present in the therapeutic formulation **5** can be higher than the amount permitted by the FDA for cough or colds. See, e.g., Handbook of Nonprescription Drugs, 10th Edition, 1993. This is so because there can be a loss of concentration for the camphor and/or menthol during the manufacturing, shipping or storage of the adhesive patch **1**. As such, the FDA allows for slightly more or slightly less (e.g., ±10%) camphor and/or menthol to be present in the stability studies.

Specifically, camphor can be present up to about 13.0 wt.% of the therapeutic formulation **5** and menthol can be present up to about 6.0 wt.% of the therapeutic formulation **5**. Preferably, camphor can be present up to about 5.9 wt.% of the therapeutic formulation **5** and menthol can be present up to about 3.2 wt.% of the therapeutic formulation **5**. More preferably, camphor can be present in about 4.2 wt.% to about 5.9 wt.% of the therapeutic formulation **5** and menthol can be present in about 2.1 wt.% to about 3.2 wt.% of the therapeutic formulation **5**.

The medicament **15** preferably can be located on and in any portion of the therapeutic formulation on the front side **3** of the backing **2**.

Preferably, the medicament **15** can be located on and in the entire portion of the therapeutic formulation. When the adhesive skin patch **1** is placed upon the skin of a patient, the medicament **15** can be in continuous contact with the skin of the patient

It has been surprisingly discovered that a suitable liquid or gel compound can be employed as a carrier, thereby obviating the need to employ conventional carriers and/or solvents (e.g., turpentine) to act as a carrier for, and preferably dissolve, the medicament **15**. Preferably, the suitable liquid or gel compound is a non-irritant. As used herein, "non-irritant" refers to an agent, e.g., organic compound, that does not produce an appreciable or significant amount of inflammation or irritation when applied topically to the skin in the specified amount.

Alternatively, the liquid or gel compound can be employed as a co-carrier, and the amount of solvent, such as a premix solvent, is lowered. The use of lower amounts of premix solvent, such as propylene glycol, allows the adhesive patch **1** to be more effectively coated during the manufacturing process. Specifically, the use of less premix solvent such as propylene glycol results in less bleed-through or leak-through of the therapeutic formulation **5** onto the back side of backing **2** in manufacturing of the adhesive patch **1**.

The suitable liquid or gel compound can act as a carrier for, and preferably can dissolve, the medicament **15**. The liquid or gel compound at least partially mask the odor of the medicament **15**, if such an odor is present. As such, the liquid or gel compound can be a fragrance. Specifically, the fragrance can be a floral scent, a food scent, a fruit scent, a plant leaf scent, or any combination thereof.

Preferably, the liquid or gel compound can maintain the stability of the medicament **15** during the manufacturing, shipping, and storage of the medicament **15**. As such, any suitable liquid or gel compound can be employed, provided that it effectively carries, and preferably dissolves the medicament **15** and the liquid or gel compound at least partially masks the odor of the medicament **15**. Preferably, the therapeutic formulation remains stable over a prolonged period of time. Preferably, the therapeutic formulation **5** retains its adhesive properties over a prolonged period of time. Preferably, if the liquid or

gel compound has an odor, the odor is pleasant. The liquid or gel compound can be an organic compound or the liquid or gel compound can be an inorganic compound. Preferably, the liquid or gel compound is an organic compound.

The liquid or gel organic liquid preferably is pharmaceutically acceptable for topical use. In addition, it is preferred that the liquid or gel organic liquid have a low to moderate volatility, so that its evaporation from the patch **1** is rendered minimal to moderate. The volatility will, however, be high enough such that when desirable, the odor or scent can be detected by the patient. Preferably, the therapeutic formulation **5** of the adhesive patch **1** will emit an odor or scent that is detected by the patient for a period of at least about 10 hours, at least about 8 hours, or at least about 6 hours.

The liquid or gel compound can be a low odor liquid or gel compound, a high odor liquid or gel compound, or a mixture thereof. As used herein, a high odor liquid or gel compound, such as a fragrance, can effectively mask the odor of another component, such as medicament **15**. Some people, especially adults, have shown a preference for topical cough formulations wherein the odor of the medicament **15** (e.g., camphor or menthol) is detectable. These cough formulations can include a liquid or gel compound that possesses a lower odor than the medicament **15**. In such situations, the odor of the medicament **15** will be more noticeable or detectable than the odor of the liquid or gel compound because the liquid or gel compound will only partially mask the odor of the medicament **15**.

It is appreciated that the suitable low odor liquid or gel compounds would be known to those skilled in the art. It is also appreciated that those skilled in the art understand that suitable low odor liquid or gel compounds are commercially available from, for example, Alpine Aromatics (Piscataway, NJ), Andrea Aromatics (Princeton, NJ), Arylessence, Inc. (Marietta, GA), Belmay Co., Inc. (Yonkers, NY), Crami Flavor & Fragrance Co., Inc. (City of Commerce, CA), Creative Fragrances Mfgr. Inc. (Dallas, TX), Drom International Co. (Tawaco, NJ), Fleurchem, Inc. (Middletown, NY), Great Lakes Chem. Corp. (Lafayette, IN), Kraus & Co., Inc. (Battle Creek, MI), The Lebermuth Co., Inc. (Mishawaka, IN), Penta Manufacturing (Livingston, NJ), Shaw Mudge & Co. (Shelton, CT), Synarome Corp. (NY, NY), Penreco

(Houston, TX), Tracy Chemical Co. (Portland, OR), Belle-Aire Fragrances (Mundelein, IL), Gusta Fragrances Co. (Chesire, CT), Atlanta Fragrance (Kennesaw, GA), and Bell Flavors & Fragrances, Inc (Northbrook, IL). It is further appreciated that those of skill in the art understand that the low odor liquid or gel compound can be any suitable low odor liquid or gel compound or compounds commercially available from, for example, the above vendors, or any combination thereof.

As the number of suitable low odor liquid or gel compounds is too voluminous and expansive to exhaustively list herein, suitable exemplary low odor liquid or gel compounds are disclosed herein. Suitable exemplary low odor liquid or gel compounds include grape fragrance, musk fragrance, light vanilla fragrance, Jergens lotion fragrance, Vaseline Intensive Care fragrance, Nivea Lotion fragrance, Ivory Soap fragrance, or any combination thereof. Preferably, a low odor liquid or gel compound that can partially mask the odor of the medicament **15** is grape fragrance, methyl anthranilate.

The low odor liquid or gel compounds can be unidentifiable. In addition, the therapeutic formulation can contain the liquid or gel compound that is of minimal odor. An unidentifiable liquid or gel compound has odor that cannot be readily identified by the average consumer. An unidentifiable liquid or gel compound does have an odor, but the odor cannot be readily identified by the average consumer. A minimally odorous liquid or gel compound is one without any distinct odor. It is not odor-free but the odor is not recognizable and exceedingly faint.

Some people, especially children, have shown a preference for topical cough formulations wherein the odor of the medicament **15** is not detectable to any appreciable degree. These cough formulations can include a liquid or gel compound that possesses a higher odor than the medicament **15**. In this situation, the odor of the medicament **15** will be less noticeable or detectable than the odor of the liquid or gel compound, such that the liquid or gel compound effectively masks the odor of the medicament **15**.

It is appreciated that the suitable high odor liquid or gel compounds would be known to those skilled in the art. It is also appreciated that those skilled in the art understand that suitable high odor liquid or gel

compounds are commercially available from, for example, Alpine Aromatics (Piscataway, NJ), Andrea Aromatics (Princeton, NJ), Arylessence, Inc. (Marietta, GA), Belmay Co., Inc. (Yonkers, NY), Crami Flavor & Fragrance Co., Inc. (City of Commerce, CA), Creative Fragrances Mfgr. Inc. (Dallas, TX), Drom International Co. (Tawaco, NJ), Fleurchem, Inc. (Middletown, NY), Great Lakes Chem. Corp. (Lafayette, IN), Kraus & Co., Inc. (Battle Creek, MI), The Lebermuth Co., Inc. (Mishawaka, IN), Penta Manufacturing (Livingston, NJ), Shaw Mudge & Co. (Shelton, CT), Synarome Corp. (NY, NY), Penreco (Houston, TX), Tracy Chemical Co. (Portland, OR), Belle-Aire Fragrances (Mundelein, IL), Gusta Fragrances Co. (Chesire, CT), Atlanta Fragrance (Kennesaw, GA), and Bell Flavors & Fragrances, Inc (Northbrook, IL). It is further appreciated that those of skill in the art understand that the high odor liquid or gel compound can be any suitable high odor liquid or gel compound or compounds commercially available from, for example, the above vendors, or any combination thereof.

As the number of suitable high odor liquid or gel compounds is too voluminous and expansive to exhaustively list herein, suitable exemplary high odor liquid or gel compounds are disclosed herein. Suitable exemplary high odor liquid or gel compounds include amaretto, blueberry, coffee, egg nog, peanut butter, rum cake, honey almond, ginger bread house, coffee cake & spice, raspberry rose, sassafras, strawberry, grapefruit pink, home sweet, jeweled citrus, lemon, mango, mulberry, orange flower, passion fruit, pikaki, freesia, china rain, coconut, apple, baked bread, cornucopia, lemon chiffon, peppermint twist, white cake, cherry pie, sugar plum, plum, romantic, sea fresh, tea, green floral, honeydew, kiwi, lilac, may bouquet, neutralizer, patchouli, peach, pine apple blossom, chocolate mint, frankincense, baked apple pie, cappuccino, cran-apple, maple syrup, popcorn (buttered), sugar cookie, cotton candy, cranberry cobbler, plumeria, rum, spring fever, watermelon, guava, honeysuckle, hyacinth, macadamia nut, melon, oakmoss, papaya, pear pineapple, blueberry, citrus-ginseng, garden dreams, banana creme pie, chocolate mint, cranberry, macadamia nut, pumpkin pie, chocolate German cake, banana nut bread, sweet potato pie, raspberry, sandalwood, spring flowers, ylang, heather, jasmine,

lavender, magnolia, mountain air, orange essence, paradise, peony, alpine breeze, chamomile, clover, gardenia, or any combination thereof.

Preferably, the high odor liquid or gel compound that can effectively mask the odor of the medicament **15** can be bubble gum, candy cane, tutti frutti, rose, green apple, cinnamon, cherry, orange sherbet, or any combination thereof. More preferably, the high odor fragrance that can effectively mask the odor of the medicament **15** can be cherry fragrance.

The fragrance can be produced from a single liquid or gel compound or from a mixture of two or more liquid or gel compounds. As such, suitable liquid or gel compounds can include (a) at least one low odor liquid or gel compound, (b) at least one high odor liquid or gel compound, (c) a combination of at least one low odor liquid or gel compound and at least one high odor liquid or gel compound, (d) preferably eucalyptus oil, and one or more of a low odor or high odor liquid or gel compound or a combination thereof. Any suitable combination of low odor liquid or gel compound, high odor liquid or gel compound, and eucalyptus oil can be employed.

An example of a suitable liquid or gel compound combination includes grape fragrance present up to about 5.0 wt.% of the therapeutic formulation **5** and eucalyptus oil present up to about 4.0 wt.% of the therapeutic formulation **5**. Preferably, the suitable liquid or gel compound includes grape essence present in about 0.5 wt.% to about 4.0 wt.% of the therapeutic formulation **5** and eucalyptus oil present in about 0.5 wt.% to about 3.0 wt.% of the therapeutic formulation **5**. More preferably, the liquid or gel compound includes grape essence present in about 0.75 wt.% to about 1.25 wt.% of the therapeutic formulation **5** and eucalyptus oil present in about 0.9 wt.% to about 1.5 wt.% of the therapeutic formulation **5**.

Any suitable pressure sensitive adhesive can be employed, provided the pressure sensitive adhesive maintains its adhesive properties and maintains the appropriate stability of the medicament **15**. Preferably, this maintenance and stability is over a prolonged period of time, e.g., at least about 2 years, at least about 1 year, or at least about 6 months, typically experienced in the manufacturing, shipping, and storage of the patch **1**. The pressure sensitive adhesive is optionally a gel.

The pressure sensitive adhesive preferably includes an acrylic ester copolymer, a polymer, and a humectant. The amount of acrylic ester copolymer employed can depend upon the specific adhesive or adhesives employed. For example, the pressure sensitive adhesive can include an acrylic ester copolymer in about 0.1 wt.% to about 50 wt.% of the therapeutic formulation **5**. Preferably, the pressure sensitive adhesive can include an acrylic ester copolymer in about 1.0 wt.% to about 25.0 wt.% of the therapeutic formulation **5**. More preferably, the pressure sensitive adhesive can include an acrylic ester copolymer in about 3.0 wt.% to about 10.0 wt.% of the therapeutic formulation **5**.

Any suitable polymer can be employed, provided the polymer maintains the adhesive properties of the pressure sensitive adhesive and maintains the appropriate stability of the medicament **15**. Suitable polymers include starch, starch derivatives, polyvinyl pyrrolidone, polyethylene oxide, polyacrylate quats, polymaleic acid, polymaleic anhydride, polyurethanes, polyureas, karaya, gum acacia, locust bean gum, xanthan gum, guar gum, modified guar gum, maltodextrin, carboxymethyl cellulose, carboxypropyl cellulose, polyacrylamide, polyvinyl alcohol, poly AMPS, and polyacrylates. Other suitable polymers are disclosed, e.g., in U.S. Patent No. 4,675,009; U.S. Patent No. 5,536,263; U.S. Patent No. 4,696,854; U.S. Patent No. 5,741,510, and references cited therein. Preferably, the polymer is karaya.

Any suitable amount of polymer can be employed, provided the amount of polymer maintains the adhesive properties of the pressure sensitive adhesive and maintains the appropriate stability of the medicament **15**. For example, karaya can be employed as the polymer in about 10 wt% to about 50 wt.% of the therapeutic formulation **5**, in about 20 wt% to about 40 wt.% of the therapeutic formulation **5**, in about 15 wt% to about 30 wt.% of the therapeutic formulation **5**, or in about 20 wt% to about 40 wt.% of the therapeutic formulation **5**. Preferably, karaya can be employed as the polymer in about 30 wt% to about 35 wt.% of the therapeutic formulation **5**.

Any suitable humectant can be employed, provided the humectant maintains the adhesive properties of the pressure sensitive adhesive and maintains the appropriate stability of the medicament **15**. The humectant

provides a moistening effect to the pressure sensitive adhesive. For example, the humectant can hydrate the polymer. Any suitable humectant can be employed, provided it hydrates the polymer. One suitable humectant is glycerin. Other suitable humectants include polyhydric alcohols such as ethylene glycol, propylene glycol, triethylene glycol, tetraethylene glycol, and sorbitol.

Any suitable humectant can be employed, provided the amount of humectant maintains the adhesive properties of the pressure sensitive adhesive and maintains the appropriate stability of the medicament **15**. The suitable humectant in part can relate to the specific polymer or polymers employed. For example, glycerin can be employed as the humectant in about 20 wt% to about 70 wt.% of the therapeutic formulation **5**, preferably about 30 wt% to about 60 wt.% of the therapeutic formulation **5**, or more preferably in about 40 wt% to about 50 wt.% of the therapeutic formulation **5**.

Alternatively, the pressure sensitive adhesive can include a hot melt pressure sensitive adhesive or solvent based pressure sensitive adhesive (e.g., polyacrylate, polyisobutylene, and polybutene), rubber, silicone based pressure sensitive adhesives (e.g., polydimethylsiloxane and resin mixtures), polystyrene-polybutadiene-polystyrene, polystyrene-polyisoprene-polystyrene, polystyrene-poly(ethylene-butylene)-polystyrene block polymers, or any combination thereof. In addition, the pressure sensitive adhesive can include a resin emulsion adhesive, wherein the resin emulsion adhesive can include vinyl acetate resin, acrylic ester copolymer, vinyl actetate/diocyl maleate copolymer, acrylic copolymer, or any combination thereof.

Other suitable pressure sensitive adhesives are disclosed, e.g., in U.S. Patent No. 4,675,009; U.S. Patent No. 5,536,263; U.S. Patent No. 4,696,854; U.S. Patent No. 5,741,510, and references cited therein.

The pressure sensitive adhesive can be located on or in any portion of the therapeutic formulation. Preferably, the pressure sensitive adhesive is located on the entire skin contact side of the therapeutic formulation. When the adhesive skin patch **1** is placed upon the skin surface of a patient, the pressure sensitive adhesive in this configuration is in continuous contact with the skin surface of the patient.

The therapeutic formulation **5** can optionally include a premix solvent. The premix solvent assists the combination of liquid or gel compound and the medicament **15**. Typically, the premix solvent can be any of the polyhydric alcohols disclosed herein above for the humectant. Suitable premix solvents include propylene glycol, ethylene glycol, triethylene glycol, tetraethylene glycol, and sorbitol.

Any suitable amount of premix solvent can be employed, provided the amount of premix solvent maintains the adhesive properties of the pressure sensitive adhesive and maintains the appropriate stability of the medicament **15**. Specifically, the premix solvent can be present up to about 20 wt.% of the therapeutic formulation **5**. Preferably, propylene glycol can be present up to about 10.0 wt.% of the therapeutic formulation **5**. More preferably, propylene glycol can be present up to about 6.0 wt.% of the therapeutic formulation **5**.

The therapeutic formulation **5** can optionally include a topical moisturizer (i.e., skin conditioner). Any suitable topical moisturizer can be employed. Suitable topical moisturizers include calamine, aloe, Vitamin E (i.e., tocopheryl), Vitamin E acetate (i.e., tocopheryl acetate), Vitamin C (i.e., L-(+)-ascorbic acid), and lanolin. As used herein, "calamine" is a pink powder of zinc oxide and a skin protectant containing about 98% zinc oxide and about 0.5% ferric oxide; "aloe" is the dried latex of leaves of Curaco Aloe (*Aloe barbadenis* Miller, *Aloe vera* Linne) or Cape Aloe (*Aloe ferox* Miller and hybrids), of the family *Liliacaea*; "Vitamin E" is 3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol; "Vitamin E acetate" is 3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol acetate; and "lanolin" is the fat-like secretion of the sebaceous glands of sheep (i.e., complex mixture of esters and polyesters of 33 high molecular weight alcohols and 36 fatty acids) which is deposited onto the wool fibers. Preferably, the topical moisturizer can be aloe. Aloe is commercially available as Aloe Vera Gel from Terry Laboratories (Melbourne, FL). Aloe Vera Gel is commercially available as Aloe Vera Gel 40X (20.0 wt.% solution in water), Aloe Vera Gel 1X (0.5 wt.% solution in water), Aloe Vera Gel 10X (5.0 wt.% solution in water), or solid Aloe Vera. The solid Aloe Vera can be dissolved in a carrier, such as

water, to the desired concentration. In addition, the commercially available forms of Aloe Vera are optionally available as decolorized Aloe Vera.

Any suitable amount of topical moisturizer can be employed, provided the amount of topical moisturizer maintains the adhesive properties of the pressure sensitive adhesive and maintains the appropriate stability of the medicament **15**. The suitable amount of topical moisturizer will depend in part upon the specific moisturizer or moisturizers present in the therapeutic formulation **5**. For example, Aloe Vera Gel, 1X can be present up to about 40.0 wt.% of the therapeutic formulation **5**. Preferably, Aloe Vera Gel, 1X can be present up to about 5.0 wt.% of the therapeutic formulation **5**. More preferably, Aloe Vera Gel, 1X can be present up to about 1.0 wt.% of the therapeutic formulation **5**.

The therapeutic formulation **5** can optionally include deionized water (DI). Any suitable amount of deionized water can be employed, provided the amount of deionized water maintains the adhesive properties of the pressure sensitive adhesive and maintains the appropriate stability of the medicament **15**. For example, deionized water can be present up to about 90 wt.% of the therapeutic formulation **5** or up to about 40.0 wt.% of the therapeutic formulation **5**. Preferably, deionized water can be present up to about 10.0 wt.% of the therapeutic formulation **5**. More preferably, deionized water can be present up to about 6.0 wt.% of the therapeutic formulation **5**.

The therapeutic formulation **5** preferably can remain stable over prolonged period of time, such as from more than about a month to more than about two years. The packaging, shipping, and storage of the adhesive skin patch **1** may have an effect upon the duration. The stability of the medicament **15** is due in part to the therapeutic formulation **5** including the medicament **15** in an adhesive formulation. The adhesive formulation is a hydrogel that holds the medicament **15** in an available form while maintaining the necessary stability, pressure sensitive adhesion and effectiveness over prolonged periods of time.

The therapeutic formulation **5** can be positioned on any portion of the front side **3** of the backing **2**. Preferably, the therapeutic formulation **5** is positioned on the entire front side **3** of the backing **2**. In this latter configuration, the therapeutic formulation **5** will be in continuous contact with the entire front

side **3**. When the adhesive skin patch **1** is placed upon the skin surface of a patient, the therapeutic formulation **5** will be in continuous contact with the skin surface of the patient.

Alternatively, a portion of the front side of the backing can contain the therapeutic formulation **5** and other portions of the front side of the backing can contain any combination of the pressure sensitive adhesive, medicament **15**, and liquid or gel compound. For example, a central circular portion of the front side of the backing can contain the therapeutic formulation **5** while the remaining ring portion of the front side contains only the pressure sensitive adhesive.

The adhesive skin patch **1** can be applied to the vicinity of a patient. The vicinity of the patient includes the patient and everything within about five feet from the patient. For example, when the patient is sleeping, resting, laying, or sitting, for example, in a bed, the vicinity of the patient will typically include the patient (e.g., patient's skin surface, patient's, hair, and patient's clothing), items usually found on or near a bed (e.g., a bed sheet, blanket, pillow, pillow case) and components of the bed (e.g., head-board, mattress, bed frame and bed post).

As shown in Figs. 9-12, the adhesive skin patch **1** can be applied to the skin surface of a patient. The adhesive skin patch **1** can be applied to any suitable location on the patient. Preferably, the adhesive skin patch **1** can be applied to the chest of the patient (as shown in Fig. 9), to the throat of the patient (as shown in Fig. 11), between the upper lip and nose of the patient (as shown in Fig. 10), or to the chin of the patient (as shown in Fig. 12). In such embodiments, the adhesive skin patch **1** is positioned or located such that the medicament **15** can be effectively inhaled by the patient (see Figs. 9-12).

The adhesive skin patch **1** can have any suitable size and shape. In addition, the adhesive skin patch **1** can be cut, as desired, to provide an adhesive skin patch **1** of a suitable size and shape. The adhesive skin patch **1** can be cut with any suitable cutting device such as a scissors, scalpel, or knife.

Preferably, the adhesive skin patch **1** may have a length of about 4 inches to about 6 inches, of about 3 inches to about 5 inches, or about 2.5 inches to about 3.0 inches. Preferably, the adhesive skin patch **1** can have a

width of about 3 inches to about 4 inches, of about 2.75 inches to about 3.75 inches, or about 1.75 inches to about 2.25 inches. Alternatively, the adhesive skin patch **1** can have a width of about 0.1 inch to about 1.0 inch, of about 0.1 inch to about 0.5 inch, or about 0.1 inch to about 0.25 inch. The adhesive skin patch **1** can have a thickness of about less than about 0.1 inch, less than about 0.01 inch, or less than about 0.001 inch.

In one specific embodiment of the present invention, the adhesive skin patch **1** can have a length of about 3.0 inches and a width of about 2.0 inches. See, Fig. 7. In another specific embodiment of the present invention, the adhesive skin patch **1** can have a length of about 3.0 inches and a width of about 0.25 inch. See, Fig. 8.

Preferably, the vapor permeable adhesive skin patch **1** is individually wrapped. Some consumers have shown a preference for adhesive skin patches that are individually wrapped. The individually wrapped vapor permeable adhesive skin patch **1** offers to the consumer the ability and convenience of being able to carry a few (e.g., 1, 2, or 3) adhesive skin patches **1** without the extra packaging material.

The invention will now be illustrated by the following non-limiting Examples.

EXAMPLES

Example 1: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.8*
Camphor	*5.9*
Propylene Glycol	*1.9*
Eucalyptus Oil	*2.4*
Cherry Fragrance	*1.0*
Glycerin	*44.0*
Aloe Vera Gel 1X	*1.0*
Karaya	*34.0*
Deionized Water	*3.0*
Pressure Sensitive Adhesive	*4.0*

Example 2: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*3.0*
Camphor	*5.9*
Propylene Glycol	*4.0*
Eucalyptus Oil	*3.0*
Cherry Fragrance	*0.5*
Glycerin	*45.6*
Aloe Vera Gel 1X	*1.0*
Karaya	*32.0*
Deionized Water	*0.0*
Pressure Sensitive Adhesive	*5.0*

Example 3: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.8*
Camphor	*4.7*
Propylene Glycol	*3.5*
Eucalyptus Oil	*1.4*
Cherry Fragrance	*1.0*
Glycerin	*46.6*
Aloe Vera Gel 1X	*1.0*
Karaya	*34.0*
Deionized Water	*1.0*
Pressure Sensitive Adhesive	*4.0*

Example 4: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.9*
Camphor	*5.2*
Propylene Glycol	*4.0*
Eucalyptus Oil	*2.4*
Cherry Fragrance	*1.0*
Glycerin	*44.0*
Aloe Vera Gel 1X	*1.0*
Karaya	*33.0*
Deionized Water	*2.0*
Pressure Sensitive Adhesive	*4.5*

Example 5: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.9*
Camphor	*4.2*
Propylene Glycol	*3.6*
Eucalyptus Oil	*0.5*
Cherry Fragrance	*1.5*
Glycerin	*45.0*
Aloe Vera Gel 1X	*0.0*
Karaya	*33.0*
Deionized Water	*3.0*
Pressure Sensitive Adhesive	*6.3*

Example 6: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.8*
Camphor	*5.9*
Propylene Glycol	*3.1*
Eucalyptus Oil	*1.2*
Cherry Fragrance	*1.0*
Glycerin	*44.0*
Aloe Vera Gel 1X	*1.0*
Karaya	*34.0*
Deionized Water	*3.0*
Pressure Sensitive Adhesive	*4.0*

Example 7: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.6*
Camphor	*4.8*
Propylene Glycol	*3.8*
Eucalyptus Oil	*1.2*
Cherry Fragrance	*1.0*
Glycerin	*44.0*
Aloe Vera Gel 1X	*1.5*
Karaya	*34.6*
Deionized Water	*2.0*
Pressure Sensitive Adhesive	*4.5*

Example 8: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.9*
Camphor	*5.8*
Propylene Glycol	*3.5*
Eucalyptus Oil	*0.8*
Cherry Fragrance	*2.0*
Glycerin	*40.0*
Aloe Vera Gel 1X	*4.0*
Karaya	*35.0*
Deionized Water	*1.0*
Pressure Sensitive Adhesive	*5.0*

Example 9: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.1*
Camphor	*4.8*
Propylene Glycol	*3.0*
Eucalyptus Oil	*2.4*
Cherry Fragrance	*1.0*
Glycerin	*40.0*
Aloe Vera Gel 1X	*2.0*
Karaya	*39.0*
Deionized Water	*1.5*
Pressure Sensitive Adhesive	*4.2*

Example 10: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*3.0*
Camphor	*5.9*
Propylene Glycol	*5.0*
Eucalyptus Oil	*1.1*
Cherry Fragrance	*2.0*
Glycerin	*45.0*
Aloe Vera Gel 1X	*0.0*
Karaya	*34.0*
Deionized Water	*0.0*
Pressure Sensitive Adhesive	*4.0*

Example 11: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.9*
Camphor	*3.5*
Propylene Glycol	*2.0*
Eucalyptus Oil	*3.0*
Cherry Fragrance	*2.0*
Glycerin	*48.0*
Aloe Vera Gel 1X	*1.6*
Karaya	*34.0*
Deionized Water	*0.0*
Pressure Sensitive Adhesive	*3.0*

Example 12: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.8*
Camphor	*4.0*
Propylene Glycol	*3.0*
Eucalyptus Oil	*1.0*
Cherry Fragrance	*3.0*
Glycerin	*43.0*
Aloe Vera Gel 1X	*1.0*
Karaya	*35.2*
Deionized Water	*3.0*
Pressure Sensitive Adhesive	*4.0*

Example 13: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*3.2*
Camphor	*6.0*
Propylene Glycol	*4.5*
Eucalyptus Oil	*1.4*
Cherry Fragrance	*1.4*
Glycerin	*46.0*
Aloe Vera Gel 1X	*1.5*
Karaya	*33.0*
Deionized Water	*0.0*
Pressure Sensitive Adhesive	*3.0*

Example 14: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*3.1*
Camphor	*4.5*
Propylene Glycol	*3.2*
Eucalyptus Oil	*1.5*
Cherry Fragrance	*2.0*
Glycerin	*40.0*
Aloe Vera Gel 1X	*1.0*
Karaya	*40.0*
Deionized Water	*0.7*
Pressure Sensitive Adhesive	*4.0*

Example 15: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*3.0*
Camphor	*4.9*
Propylene Glycol	*1.5*
Eucalyptus Oil	*2.6*
Cherry Fragrance	*0.5*
Glycerin	*42.0*
Aloe Vera Gel 1X	*1.0*
Karaya	*38.0*
Deionized Water	*0.5*
Pressure Sensitive Adhesive	*6.0*

Example 16: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.9*
Camphor	*5.1*
Propylene Glycol	*1.8*
Eucalyptus Oil	*0.9*
Cherry Fragrance	*0.8*
Glycerin	*44.0*
Aloe Vera Gel 1X	*2.0*
Karaya	*30.0*
Deionized Water	*3.0*
Pressure Sensitive Adhesive	*9.5*

Example 17: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.8*
Camphor	*5.3*
Propylene Glycol	*3.5*
Eucalyptus Oil	*1.0*
Cherry Fragrance	*2.6*
Glycerin	*43.0*
Aloe Vera Gel 1X	*1.5*
Karaya	*34.0*
Deionized Water	*1.0*
Pressure Sensitive Adhesive	*5.3*

Example 18: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.7*
Camphor	*5.6*
Propylene Glycol	*3.6*
Eucalyptus Oil	*1.3*
Cherry Fragrance	*2.0*
Glycerin	*48.5*
Aloe Vera Gel 1X	*3.0*
Karaya	*30.0*
Deionized Water	*0.5*
Pressure Sensitive Adhesive	*2.8*

Example 19: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.6*
Camphor	*5.9*
Propylene Glycol	*3.4*
Eucalyptus Oil	*1.7*
Cherry Fragrance	*1.6*
Glycerin	*46.0*
Aloe Vera Gel 1X	*3.8*
Karaya	*31.0*
Deionized Water	*1.0*
Pressure Sensitive Adhesive	*3.0*

Example 20: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.5*
Camphor	*6.1*
Propylene Glycol	*4.4*
Eucalyptus Oil	*2.8*
Cherry Fragrance	*0.8*
Glycerin	*45.0*
Aloe Vera Gel 1X	*2.5*
Karaya	*32.0*
Deionized Water	*0.0*
Pressure Sensitive Adhesive	*3.9*

Example 21: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*3.0*
Camphor	*4.0*
Propylene Glycol	*3.2*
Eucalyptus Oil	*1.3*
Cherry Fragrance	*2.5*
Glycerin	*48.0*
Aloe Vera Gel 1X	*2.0*
Karaya	*33.0*
Deionized Water	*0.0*
Pressure Sensitive Adhesive	*3.0*

Example 22: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.6*
Camphor	*5.7*
Propylene Glycol	*3.0*
Eucalyptus Oil	*1.0*
Cherry Fragrance	*2.0*
Glycerin	*43.0*
Aloe Vera Gel 1X	*1.0*
Karaya	*34.7*
Deionized Water	*3.0*
Pressure Sensitive Adhesive	*4.0*

Example 23: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.8*
Camphor	*5.9*
Propylene Glycol	*1.9*
Eucalyptus Oil	*2.4*
Grape Fragrance	*1.0*
Glycerin	*44.0*
Aloe Vera Gel 1X	*1.0*
Karaya	*34.0*
Deionized Water	*3.0*
Pressure Sensitive Adhesive	*4.0*

Example 24: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*3.0*
Camphor	*5.9*
Propylene Glycol	*4.0*
Eucalyptus Oil	*3.0*
Grape Fragrance	*0.5*
Glycerin	*45.6*
Aloe Vera Gel 1X	*1.0*
Karaya	*32.0*
Deionized Water	*0.0*
Pressure Sensitive Adhesive	*5.0*

Example 25: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.8*
Camphor	*4.7*
Propylene Glycol	*3.5*
Eucalyptus Oil	*1.4*
Grape Fragrance	*1.0*
Glycerin	*46.6*
Aloe Vera Gel 1X	*1.0*
Karaya	*34.0*
Deionized Water	*1.0*
Pressure Sensitive Adhesive	*4.0*

Example 26: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.9*
Camphor	*5.2*
Propylene Glycol	*4.0*
Eucalyptus Oil	*2.4*
Grape Fragrance	*1.0*
Glycerin	*44.0*
Aloe Vera Gel 1X	*1.0*
Karaya	*33.0*
Deionized Water	*2.0*
Pressure Sensitive Adhesive	*4.5*

Example 27: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.9*
Camphor	*4.2*
Propylene Glycol	*3.6*
Eucalyptus Oil	*0.5*
Grape Fragrance	*1.5*
Glycerin	*45.0*
Aloe Vera Gel 1X	*0.0*
Karaya	*33.0*
Deionized Water	*3.0*
Pressure Sensitive Adhesive	*6.3*

Example 28: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.8*
Camphor	*5.9*
Propylene Glycol	*3.1*
Eucalyptus Oil	*1.2*
Grape Fragrance	*1.0*
Glycerin	*44.0*
Aloe Vera Gel 1X	*1.0*
Karaya	*34.0*
Deionized Water	*3.0*
Pressure Sensitive Adhesive	*4.0*

Example 29: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.6*
Camphor	*4.8*
Propylene Glycol	*3.8*
Eucalyptus Oil	*1.2*
Grape Fragrance	*1.0*
Glycerin	*44.0*
Aloe Vera Gel 1X	*1.5*
Karaya	*34.6*
Deionized Water	*2.0*
Pressure Sensitive Adhesive	*4.5*

Example 30: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.9*
Camphor	*5.8*
Propylene Glycol	*3.5*
Eucalyptus Oil	*0.8*
Grape Fragrance	*2.0*
Glycerin	*40.0*
Aloe Vera Gel 1X	*4.0*
Karaya	*35.0*
Deionized Water	*1.0*
Pressure Sensitive Adhesive	*5.0*

Example 31: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.1*
Camphor	*4.8*
Propylene Glycol	*3.0*
Eucalyptus Oil	*2.4*
Grape Fragrance	*1.0*
Glycerin	*40.0*
Aloe Vera Gel 1X	*2.0*
Karaya	*39.0*
Deionized Water	*1.5*
Pressure Sensitive Adhesive	*4.2*

Example 32: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*3.0*
Camphor	*5.9*
Propylene Glycol	*5.0*
Eucalyptus Oil	*1.1*
Grape Fragrance	*2.0*
Glycerin	*45.0*
Aloe Vera Gel 1X	*0.0*
Karaya	*34.0*
Deionized Water	*0.0*
Pressure Sensitive Adhesive	*4.0*

Example 33: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.9*
Camphor	*3.5*
Propylene Glycol	*2.0*
Eucalyptus Oil	*3.0*
Grape Fragrance	*2.0*
Glycerin	*48.0*
Aloe Vera Gel 1X	*1.6*
Karaya	*34.0*
Deionized Water	*0.0*
Pressure Sensitive Adhesive	*3.0*

Example 34: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.8*
Camphor	*4.0*
Propylene Glycol	*3.0*
Eucalyptus Oil	*1.0*
Grape Fragrance	*3.0*
Glycerin	*43.0*
Aloe Vera Gel 1X	*1.0*
Karaya	*35.2*
Deionized Water	*3.0*
Pressure Sensitive Adhesive	*4.0*

Example 35: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*3.2*
Camphor	*6.0*
Propylene Glycol	*4.5*
Eucalyptus Oil	*1.4*
Grape Fragrance	*1.4*
Glycerin	*46.0*
Aloe Vera Gel 1X	*1.5*
Karaya	*33.0*
Deionized Water	*0.0*
Pressure Sensitive Adhesive	*3.0*

Example 36: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*3.1*
Camphor	*4.5*
Propylene Glycol	*3.2*
Eucalyptus Oil	*1.5*
Grape Fragrance	*2.0*
Glycerin	*40.0*
Aloe Vera Gel 1X	*1.0*
Karaya	*40.0*
Deionized Water	*0.7*
Pressure Sensitive Adhesive	*4.0*

Example 37: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*3.0*
Camphor	*4.9*
Propylene Glycol	*1.5*
Eucalyptus Oil	*2.6*
Grape Fragrance	*0.5*
Glycerin	*42.0*
Aloe Vera Gel 1X	*1.0*
Karaya	*38.0*
Deionized Water	*0.5*
Pressure Sensitive Adhesive	*6.0*

Example 38: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.9*
Camphor	*5.1*
Propylene Glycol	*1.8*
Eucalyptus Oil	*0.9*
Grape Fragrance	*0.8*
Glycerin	*44.0*
Aloe Vera Gel 1X	*2.0*
Karaya	*30.0*
Deionized Water	*3.0*
Pressure Sensitive Adhesive	*9.5*

Example 39: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.8*
Camphor	*5.3*
Propylene Glycol	*3.5*
Eucalyptus Oil	*1.0*
Grape Fragrance	*2.6*
Glycerin	*43.0*
Aloe Vera Gel 1X	*1.5*
Karaya	*34.0*
Deionized Water	*1.0*
Pressure Sensitive Adhesive	*5.3*

Example 40: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.7*
Camphor	*5.6*
Propylene Glycol	*3.6*
Eucalyptus Oil	*1.3*
Grape Fragrance	*2.0*
Glycerin	*48.5*
Aloe Vera Gel 1X	*3.0*
Karaya	*30.0*
Deionized Water	*0.5*
Pressure Sensitive Adhesive	*2.8*

Example 41: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.6*
Camphor	*5.9*
Propylene Glycol	*3.4*
Eucalyptus Oil	*1.7*
Grape Fragrance	*1.6*
Glycerin	*46.0*
Aloe Vera Gel 1X	*3.8*
Karaya	*31.0*
Deionized Water	*1.0*
Pressure Sensitive Adhesive	*3.0*

Example 42: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.5*
Camphor	*6.1*
Propylene Glycol	*4.4*
Eucalyptus Oil	*2.8*
Grape Fragrance	*0.8*
Glycerin	*45.0*
Aloe Vera Gel 1X	*2.5*
Karaya	*32.0*
Deionized Water	*0.0*
Pressure Sensitive Adhesive	*3.9*

Example 43: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*3.0*
Camphor	*4.0*
Propylene Glycol	*3.2*
Eucalyptus Oil	*1.3*
Grape Fragrance	*2.5*
Glycerin	*48.0*
Aloe Vera Gel 1X	*2.0*
Karaya	*33.0*
Deionized Water	*0.0*
Pressure Sensitive Adhesive	*3.0*

Example 44: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.6*
Camphor	*5.7*
Propylene Glycol	*3.0*
Eucalyptus Oil	*1.0*
Grape Fragrance	*2.0*
Glycerin	*43.0*
Aloe Vera Gel 1X	*1.0*
Karaya	*34.7*
Deionized Water	*3.0*
Pressure Sensitive Adhesive	*4.0*

Example 45: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*3.0*
Camphor	*4.8*
Propylene Glycol	*3.2*
Eucalyptus Oil	*1.0*
Cherry Fragrance	*1.0*
Glycerin	*2.0*
Polyethylene oxide	*3.0*
Deionized Water	*80.0*
Pressure Sensitive Adhesives	*2.0*

Example 46: Therapeutic Formulation (in wt.%)

	Specific Embodiment
Component	**(Weight %)**
Menthol	*2.8*
Camphor	*4.0*
Propylene Glycol	*2.5*
Eucalyptus Oil	*0.7*
Grape Fragrance	*1.0*
Glycerin	*1.0*
Polyethylene Oxide	*3.0*
Deionized Water	*83.0*
Pressure Sensitive Adhesive	*2.0*

The vapor permeable adhesive patch of the present invention can be formulated or manufactured employing the above components. The vapor permeable adhesive patch of the present invention can be formulated or manufactured using any suitable technique. Preferably, the vapor permeable adhesive patch can be formulated or manufactured as described in U.S. Patent No. 5,536,263 and U.S. Patent No. 5,741,510, and references cited therein; wherein the oil premix includes menthol, camphor, propylene glycol, and a

fragrance; the glycerin premix includes glycerin and aloe vera gel; and the adhesive premix includes the adhesive and water.

All publications, patents, and patent documents cited herein are incorporated by reference herein, as though individually incorporated by reference. The invention has been described with reference to various specific and preferred embodiments and techniques. However, it should be understood that many variations and modifications may be made while remaining within the spirit and scope of the invention.

What is claimed is:

1. A vapor permeable adhesive patch comprising a backing of a flexible sheet of water insoluble porous material, the backing having a front side and a back side and a therapeutic formulation positioned on at least a portion of the front side; wherein the therapeutic formulation comprises:

a medicament for relief of coughing;

a liquid or gel compound that at least partially masks the odor of the medicament; and

a pressure sensitive adhesive.

2. The patch of claim 1 wherein the therapeutic formulation is positioned on the entire front side of the backing.

3. The patch of claim 1 wherein the backing comprises a nonwoven fabric.

4. The patch of claim 1 wherein the backing comprises polycellulose fibers, polyester fibers, polyurethane fibers, polyolefin fibers, polyamide fibers, cotton fibers, or any mixture thereof.

5. The patch of claim 1 wherein the backing comprises open cell foam.

6. The patch of claim 5 wherein the open cell foam comprises polyurethane, polyvinyl chloride, or polyethylene.

7. The patch of claim 1 wherein upon contact with skin, the backing retains the therapeutic formulation and the patch allows moisture from the skin to pass.

8. The patch of claim 1 wherein the medicament is a topical antitussive.

9. The patch of claim 8 wherein the topical antitussive is camphor, menthol, eucalyptus oil, turpentine oil, thymol, or a combination thereof.

10. The patch of claim 8 wherein the topical antitussive is camphor, menthol, or a combination thereof.

11. The patch of claim 9 wherein the camphor is present up to about 13 wt.% of the therapeutic formulation and the menthol is present up to about 6 wt.% of the therapeutic formulation.

12. The patch of claim 9 wherein the camphor is present up to about 5.9 wt.% of the therapeutic formulation and the menthol is present up to about 3.2 wt.% of the therapeutic formulation.

13. The patch of claim 1 wherein the liquid or gel compound is a fragrance.

14. The patch of claim 13 wherein the fragrance is a floral scent, a fruit scent, a plant leaf scent, or any combination thereof.

15. The patch of claim 13 wherein the fragrance is grape fragrance, musk fragrance, light vanilla fragrance, Jergens lotion fragrance, Vaseline Intensive Care fragrance, Nivea Lotion fragrance, Ivory Soap fragrance, amaretto fragrance, blueberry fragrance, coffee fragrance, egg nog fragrance, peanut butter fragrance, rum cake fragrance, honey almond fragrance, ginger bread house fragrance, coffee cake & spice fragrance, raspberry rose fragrance, sassafras fragrance, strawberry fragrance, grapefruit pink fragrance, home sweet fragrance, jeweled citrus fragrance, lemon, mango fragrance, mulberry fragrance, orange flower fragrance, passion fruit fragrance, pikaki fragrance, freesia fragrance,

china rain fragrance, coconut fragrance, apple fragrance, baked bread fragrance, cornucopia fragrance, lemon chiffon fragrance, peppermint twist fragrance, white cake fragrance, cherry pie fragrance, sugar plum fragrance, plum fragrance, romantic fragrance, sea fresh fragrance, tea fragrance, green floral fragrance, honeydew fragrance, kiwi fragrance, lilac fragrance, may bouquet fragrance, neutralizer fragrance, patchouli fragrance, peach fragrance, pine apple blossom fragrance, chocolate mint fragrance, frankincense fragrance, baked apple pie fragrance, cappuccino fragrance, cran-apple fragrance, maple syrup fragrance, buttered popcorn fragrance, sugar cookie fragrance, cotton candy fragrance, cranberry cobbler fragrance, plumeria fragrance, rum fragrance, spring fever fragrance, watermelon fragrance, guava fragrance, honeysuckle fragrance, hyacinth fragrance, macadamia nut fragrance, melon fragrance, oakmoss fragrance, papaya fragrance, pear pineapple fragrance, blueberry fragrance, citrus-ginseng fragrance, garden dreams fragrance, banana creme pie fragrance, chocolate mint fragrance, cranberry fragrance, macadamia nut fragrance, pumpkin pie fragrance, chocolate German cake fragrance, banana nut bread fragrance, sweet potato pie fragrance, raspberry fragrance, sandalwood fragrance, spring flowers fragrance, ylang fragrance, heather fragrance, jasmine fragrance, lavender fragrance, magnolia fragrance, mountain air fragrance, orange essence fragrance, paradise fragrance, peony fragrance, alpine breeze fragrance, chamomile fragrance, clover fragrance, gardenia fragrance, or any combination thereof.

16. The patch of claim 1 wherein the liquid or gel compound is eucalyptus oil, grape essence, cherry essence, or a combination thereof.

17. The patch of claim 16 wherein the eucalyptus oil is present up to about 4 wt.% of the therapeutic formulation.

18. The patch of claim 16 wherein the grape essence is present up to about 5 wt.% of the therapeutic formulation.

19. The patch of claim 16 wherein the cherry essence is present up to about 5 wt.% of the therapeutic formulation.

20. The patch of claim 1 wherein the pressure sensitive adhesive comprises an acrylic ester copolymer, a polymer, and a humectant.

21. The patch of claim 20 wherein the acrylic ester copolymer is present in about 2 wt.% to about 25 wt.% of the therapeutic formulation.

22. The patch of claim 20 wherein the polymer is karaya, gum acacia, locust bean gum, xanthan gum, guar gum, modified guar gum, maltodextrin, carboxymethyl cellulose, carboxypropyl cellulose, polyacrylamide, polyvinyl alcohol, poly AMPS, a polyacrylate, or a mixture thereof.

23. The patch of claim 20 wherein the polymer is polyvinyl pyrrolidone, polyethylene oxide, polyacrylate quat, polymaleic acid, polymaleic anhydride, polyurethane, polyurea, or a combination thereof.

24. The patch of claim 20 wherein the polymer is karaya which is present in about 20 wt.% to about 40 wt.% of the therapeutic formulation.

25. The patch of claim 20 wherein the humectant is glycerin.

26. The patch of claim 25 wherein the glycerin is present in about 40 wt.% to about 50 wt.% of the therapeutic formulation.

27. The patch of claim 1 wherein the pressure sensitive adhesive is positioned on the entire front side of the backing.

28. The patch of claim 1 wherein the therapeutic formulation further comprises aloe, lanolin, glycerin, Vitamin E, Vitamin E acetate, Vitamin C, or a combination thereof.

29. The patch of claim 1 wherein the therapeutic formulation further comprises a premix solvent.

30. The patch of claim 29 wherein the premix solvent is a polyhydric alcohol.

31. The patch of claim 30 wherein the polyhydric alcohol is ethylene glycol, propylene glycol, triethylene glycol, tetraethylene glycol, sorbitol, or a combination thereof.

32. The patch of claim 30 wherein the polyhydric alcohol is present in about 20 wt% to about 70 wt.% of the therapeutic formulation.

33. The patch of claim 30 wherein the premix solvent is present up to about 6 wt.% of the therapeutic formulation.

34. The patch of claim 1 that is individually wrapped.

35. A vapor permeable adhesive patch comprising a backing of a flexible sheet of water insoluble porous material, the backing having a front side and a back side and a therapeutic formulation positioned on the front side of the backing; wherein the therapeutic formulation comprises:

a medicament for relief of coughing;

a liquid or gel compound that at least partially masks the odor of the medicament; and

a pressure sensitive adhesive; useful to alleviate coughing in a human.

36. The patch of claim 35 wherein the medicament for relief of coughing is a topical antitussive.

37. The patch of claim 36 wherein the antitussive is camphor, menthol, eucalyptus oil, turpentine oil, thymol, or a combination thereof.

38. The patch of claim 36 wherein the antitussive is camphor, menthol, or a combination thereof.

39. The patch of claim 37 wherein the camphor is present up to about 13 wt.% of the therapeutic formulation and the menthol is present up to about 6 wt.% of the therapeutic formulation.

40. The patch of claim 37 wherein the camphor is present up to about 5.9 wt.% of the therapeutic formulation and the menthol is present up to about 3.2 wt.% of the therapeutic formulation.

41. The patch of claim 35 wherein the liquid or gel compound is a fragrance.

42. The patch of claim 41 wherein the fragrance is grape fragrance, musk fragrance, light vanilla fragrance, Jergens lotion fragrance, Vaseline Intensive Care fragrance, Nivea Lotion fragrance, Ivory Soap fragrance, amaretto fragrance, blueberry fragrance, coffee fragrance, egg nog fragrance, peanut butter fragrance, rum cake fragrance, honey almond fragrance, ginger bread house fragrance, coffee cake & spice fragrance, raspberry rose fragrance, sassafras fragrance, strawberry fragrance, grapefruit pink fragrance, home sweet fragrance, jeweled citrus fragrance, lemon, mango fragrance, mulberry fragrance, orange flower fragrance, passion fruit fragrance, pikaki fragrance, freesia fragrance, china rain fragrance, coconut fragrance, apple fragrance, baked bread fragrance, cornucopia fragrance, lemon chiffon fragrance, peppermint twist fragrance, white cake fragrance, cherry pie fragrance, sugar plum fragrance, plum

fragrance, romantic fragrance, sea fresh fragrance, tea fragrance, green floral fragrance, honeydew fragrance, kiwi fragrance, lilac fragrance, may bouquet fragrance, neutralizer fragrance, patchouli fragrance, peach fragrance, pine apple blossom fragrance, chocolate mint fragrance, frankincense fragrance, baked apple pie fragrance, cappuccino fragrance, cran-apple fragrance, maple syrup fragrance, buttered popcorn fragrance, sugar cookie fragrance, cotton candy fragrance, cranberry cobbler fragrance, plumeria fragrance, rum fragrance, spring fever fragrance, watermelon fragrance, guava fragrance, honeysuckle fragrance, hyacinth fragrance, macadamia nut fragrance, melon fragrance, oakmoss fragrance, papaya fragrance, pear pineapple fragrance, blueberry fragrance, citrus-ginseng fragrance, garden dreams fragrance, banana creme pie fragrance, chocolate mint fragrance, cranberry fragrance, macadamia nut fragrance, pumpkin pie fragrance, chocolate German cake fragrance, banana nut bread fragrance, sweet potato pie fragrance, raspberry fragrance, sandalwood fragrance, spring flowers fragrance, ylang fragrance, heather fragrance, jasmine fragrance, lavender fragrance, magnolia fragrance, mountain air fragrance, orange essence fragrance, paradise fragrance, peony fragrance, alpine breeze fragrance, chamomile fragrance, clover fragrance, gardenia fragrance, or any combination thereof.

43. The patch of claim 41 wherein the fragrance is a floral scent, a fruit scent, a plant leaf scent, or any combination thereof.

44. The patch of claim 35 wherein the liquid or gel compound is eucalyptus oil, grape essence, cherry essence, or a combination thereof.

45. The patch of claim 44 wherein the eucalyptus oil is present up to about 4 wt.% of the therapeutic formulation.

46. The patch of claim 44 wherein the grape essence is present up to about 5 wt.% of the therapeutic formulation.

47. The patch of claim 44 wherein the cherry essence is present up to about 5 wt.% of the therapeutic formulation.

48. The patch of any one of claim 1-47 that is useful to alleviate or relieve coughing in a human.

49. A vapor permeable adhesive patch comprising a backing of a flexible sheet of water insoluble porous material, the backing having a front side and a back side and a therapeutic formulation positioned on at least a portion of the front side; wherein the therapeutic formulation comprises:

a medicament for relief of coughing;

a liquid or gel compound that at least partially masks the odor of the medicament; and

a pressure sensitive adhesive; useful to alleviate or relieve coughing in a human.

50. wherein the medicament for relief of coughing is a topical antitussive.

51. The patch of claim 50 wherein the antitussive is camphor, menthol, eucalyptus oil, turpentine oil, thymol, or a combination thereof.

52. The patch of claim 50 wherein the antitussive is camphor, menthol, or a combination thereof.

53. The patch of claim 51 wherein the camphor is present up to about 13 wt.% of the therapeutic formulation and the menthol is present up to about 6 wt.% of the therapeutic formulation.

54. The patch of claim 51 wherein the camphor is present up to about 5.9 wt.% of the therapeutic formulation and the menthol is present up to about 3.2 wt.% of the therapeutic formulation.

55. The patch of claim 51 wherein the liquid or gel compound is a fragrance.

56. The patch of claim 41 wherein the fragrance is grape fragrance, musk fragrance, light vanilla fragrance, Jergens lotion fragrance, Vaseline Intensive Care fragrance, Nivea Lotion fragrance, Ivory Soap fragrance, amaretto fragrance, blueberry fragrance, coffee fragrance, egg nog fragrance, peanut butter fragrance, rum cake fragrance, honey almond fragrance, ginger bread house fragrance, coffee cake & spice fragrance, raspberry rose fragrance, sassafras fragrance, strawberry fragrance, grapefruit pink fragrance, home sweet fragrance, jeweled citrus fragrance, lemon, mango fragrance, mulberry fragrance, orange flower fragrance, passion fruit fragrance, pikaki fragrance, freesia fragrance, china rain fragrance, coconut fragrance, apple fragrance, baked bread fragrance, cornucopia fragrance, lemon chiffon fragrance, peppermint twist fragrance, white cake fragrance, cherry pie fragrance, sugar plum fragrance, plum fragrance, romantic fragrance, sea fresh fragrance, tea fragrance, green floral fragrance, honeydew fragrance, kiwi fragrance, lilac fragrance, may bouquet fragrance, neutralizer fragrance, patchouli fragrance, peach fragrance, pine apple blossom fragrance, chocolate mint fragrance, frankincense fragrance, baked apple pie fragrance, cappuccino fragrance, cran-apple fragrance, maple syrup fragrance, buttered popcorn fragrance, sugar cookie fragrance, cotton candy fragrance, cranberry cobbler fragrance, plumeria fragrance, rum fragrance, spring fever fragrance, watermelon fragrance, guava fragrance, honeysuckle fragrance, hyacinth fragrance, macadamia nut fragrance, melon fragrance, oakmoss fragrance, papaya fragrance, pear pineapple fragrance, blueberry fragrance, citrus-ginseng fragrance, garden dreams fragrance, banana creme pie fragrance, chocolate mint fragrance, cranberry fragrance, macadamia nut fragrance, pumpkin pie fragrance, chocolate German cake fragrance, banana nut bread fragrance, sweet potato pie fragrance, raspberry fragrance, sandalwood fragrance, spring flowers fragrance, ylang fragrance, heather fragrance, jasmine fragrance, lavender fragrance, magnolia fragrance, mountain air fragrance, orange essence fragrance, paradise fragrance, peony fragrance, alpine breeze fragrance,

chamomile fragrance, clover fragrance, gardenia fragrance, or any combination thereof.

57. The patch of claim 56 wherein the fragrance is a floral scent, a fruit scent, a plant leaf scent, or any combination thereof.

58. The patch of claim 50 wherein the liquid or gel compound is eucalyptus oil, grape essence, cherry essence, or a combination thereof.

59. The patch of claim 58 wherein the eucalyptus oil is present up to about 4 wt.% of the therapeutic formulation.

60. The patch of claim 58 wherein the grape essence is present up to about 5 wt.% of the therapeutic formulation.

61. The patch of claim 58 wherein the cherry essence is present up to about 5 wt.% of the therapeutic formulation.

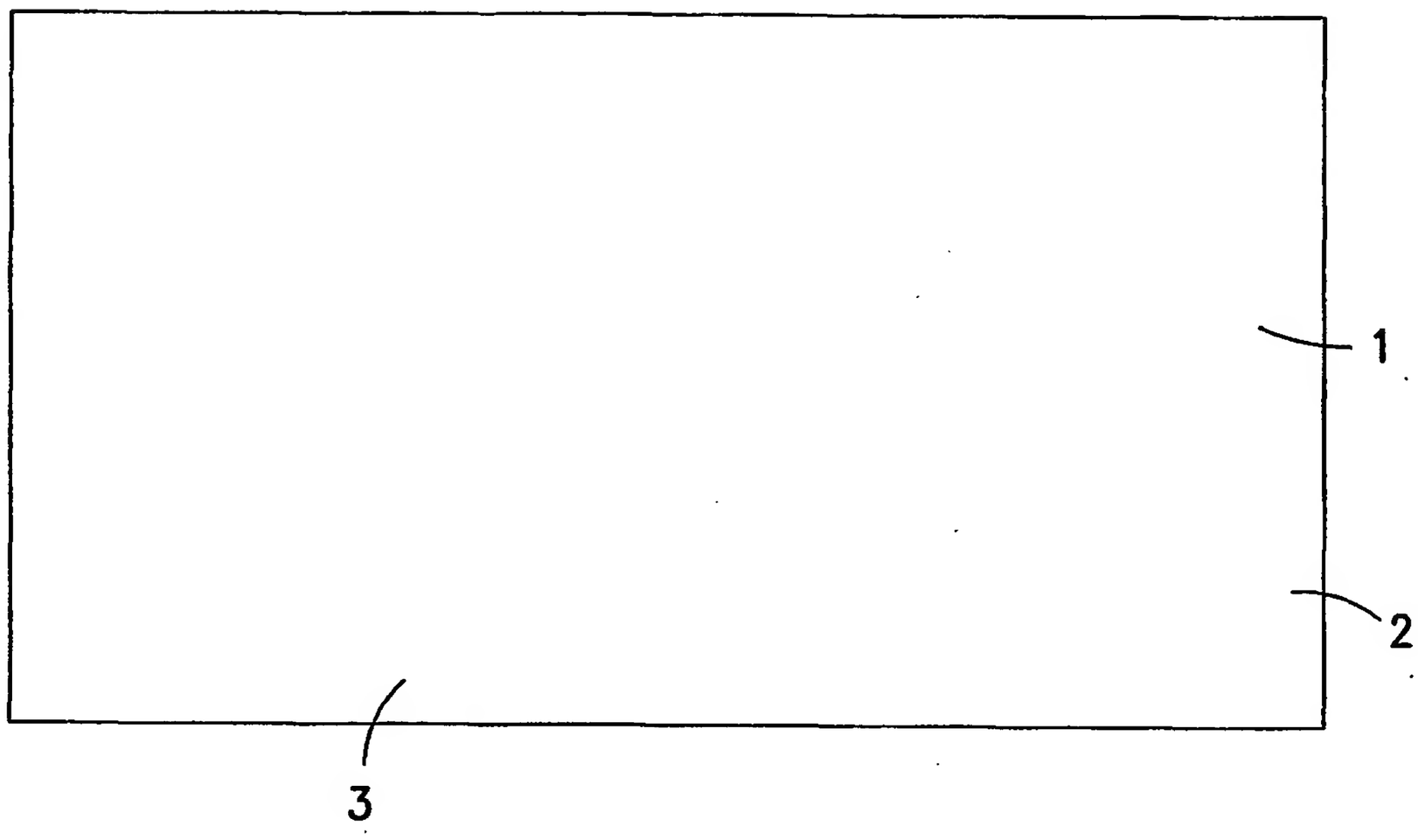

FIG. 1

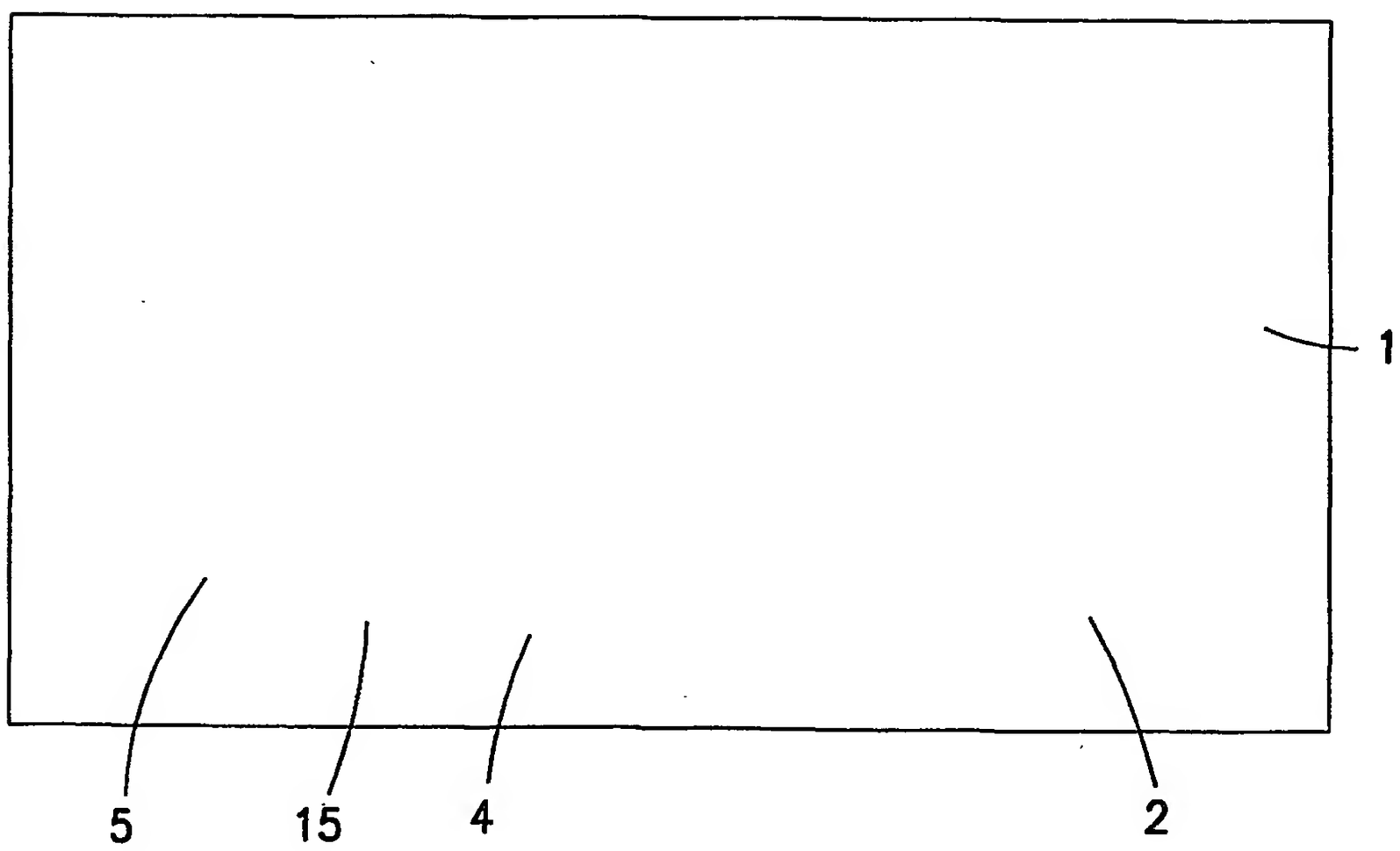

FIG. 2

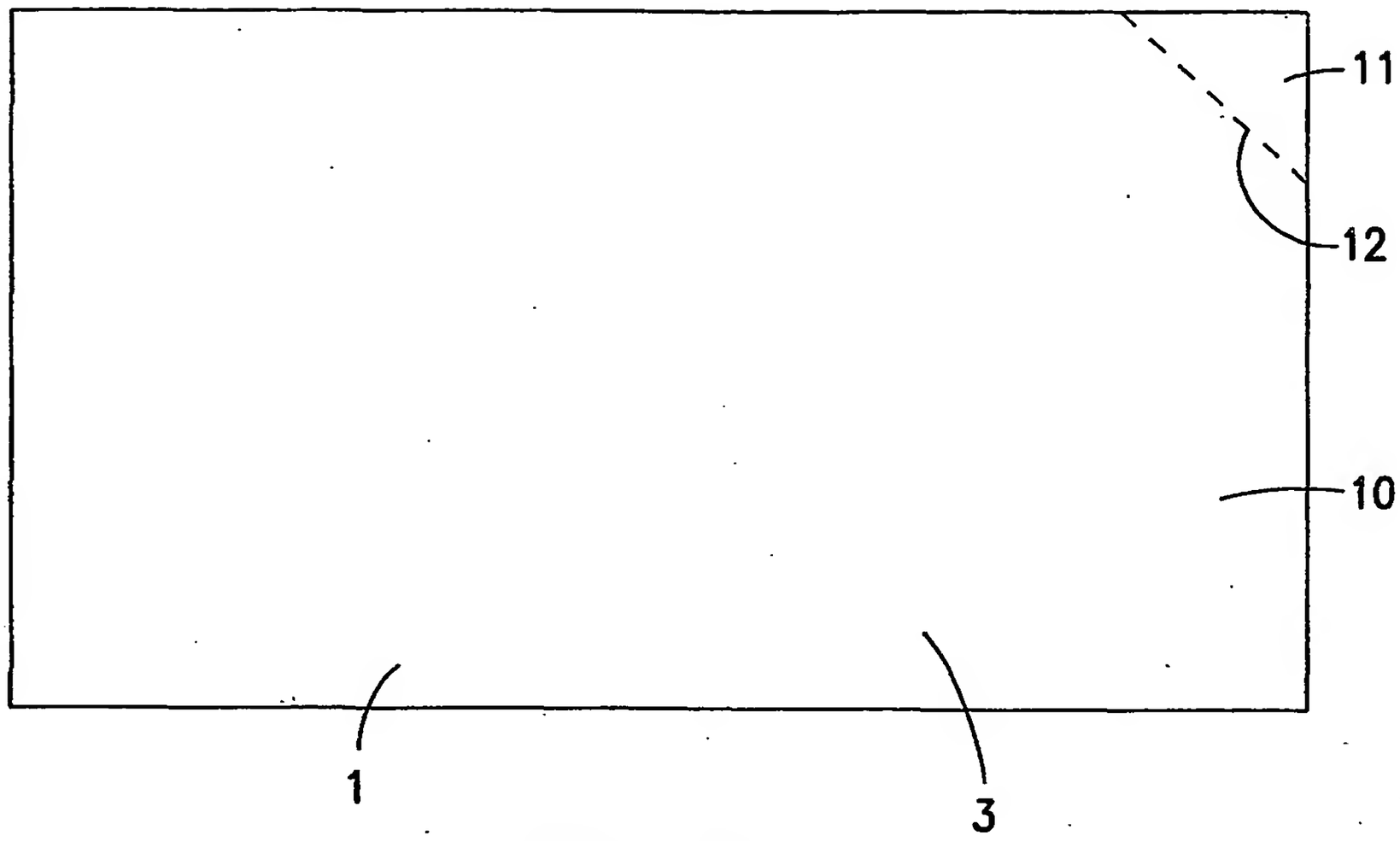

FIG. 3

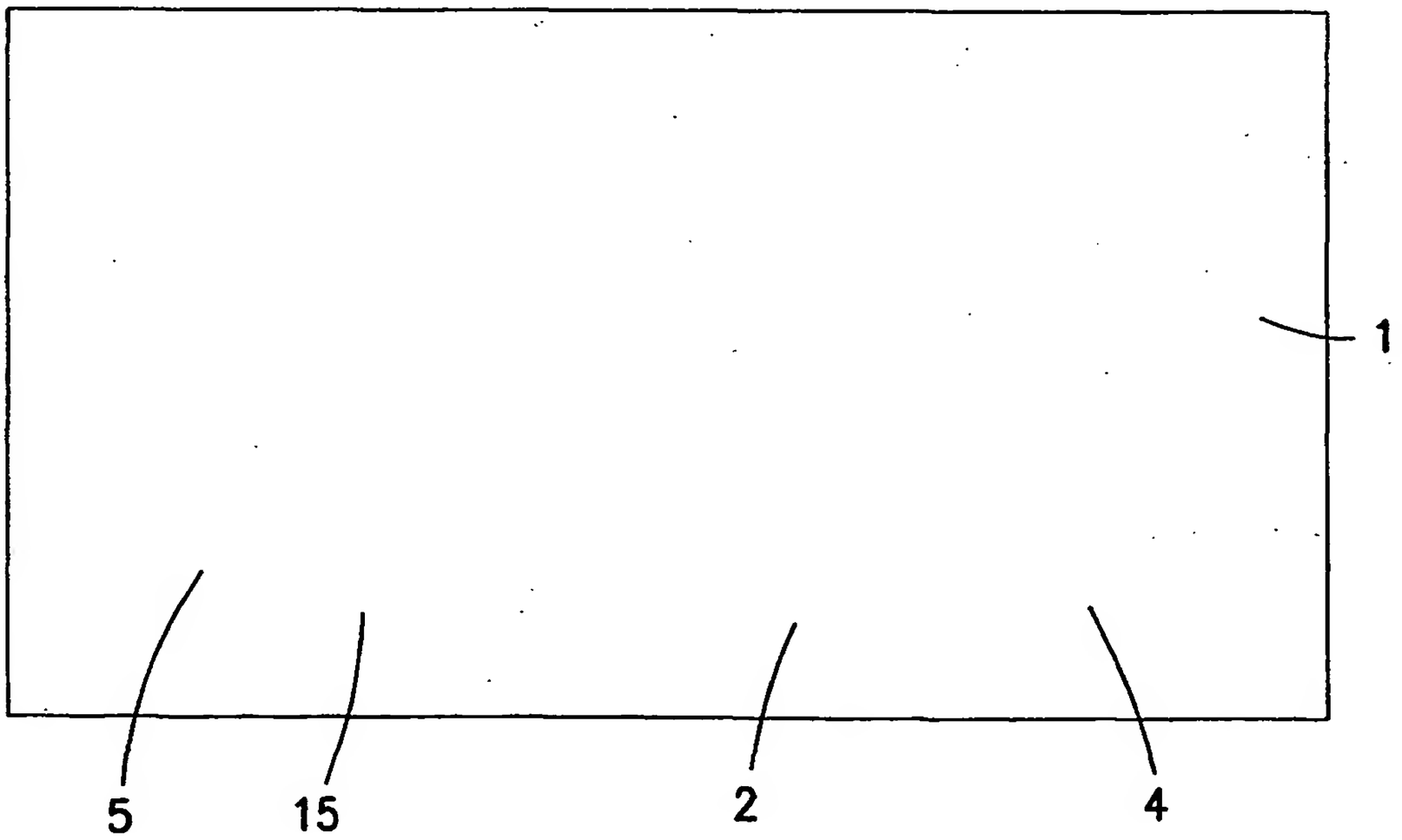

FIG. 4

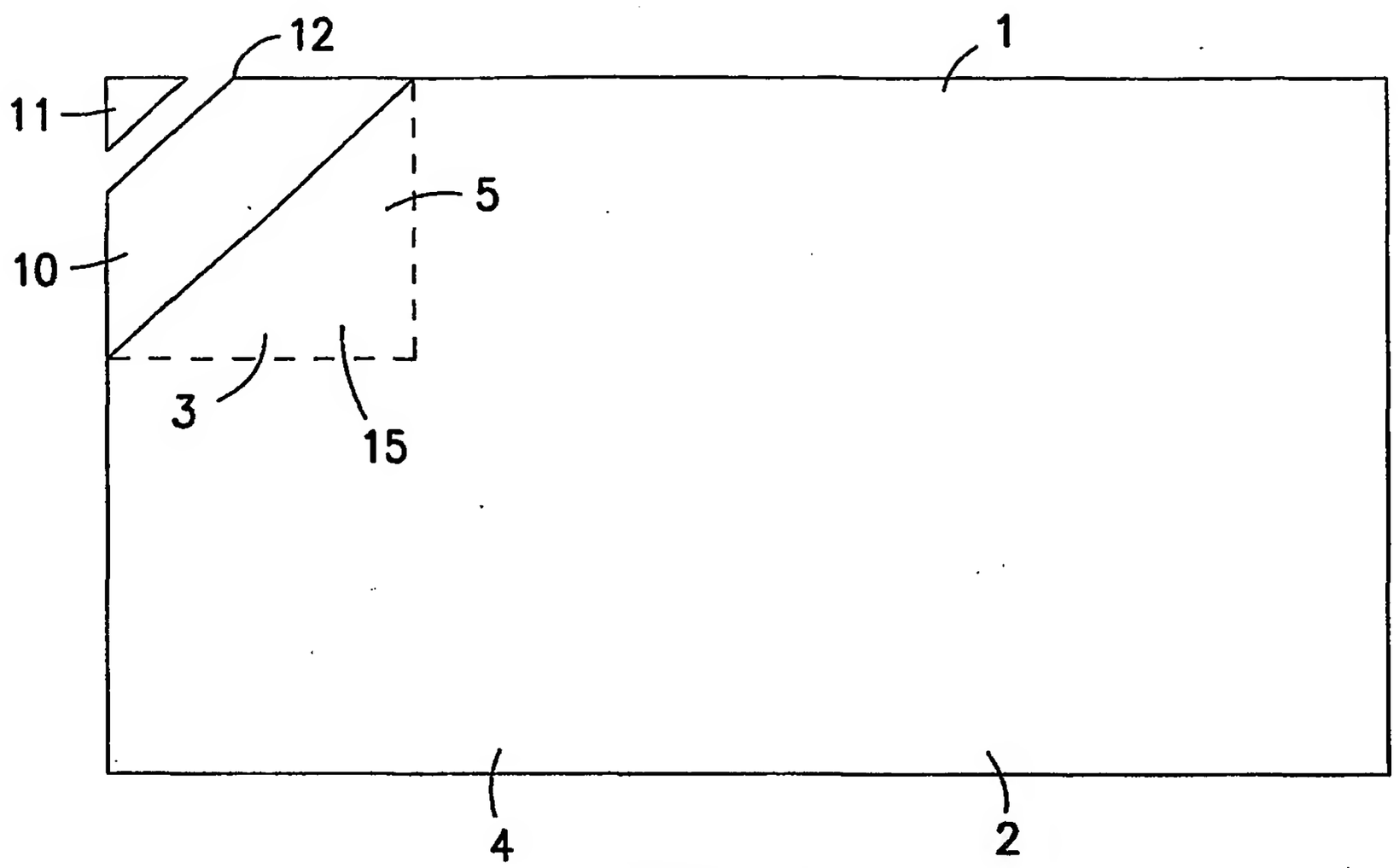

FIG. 5

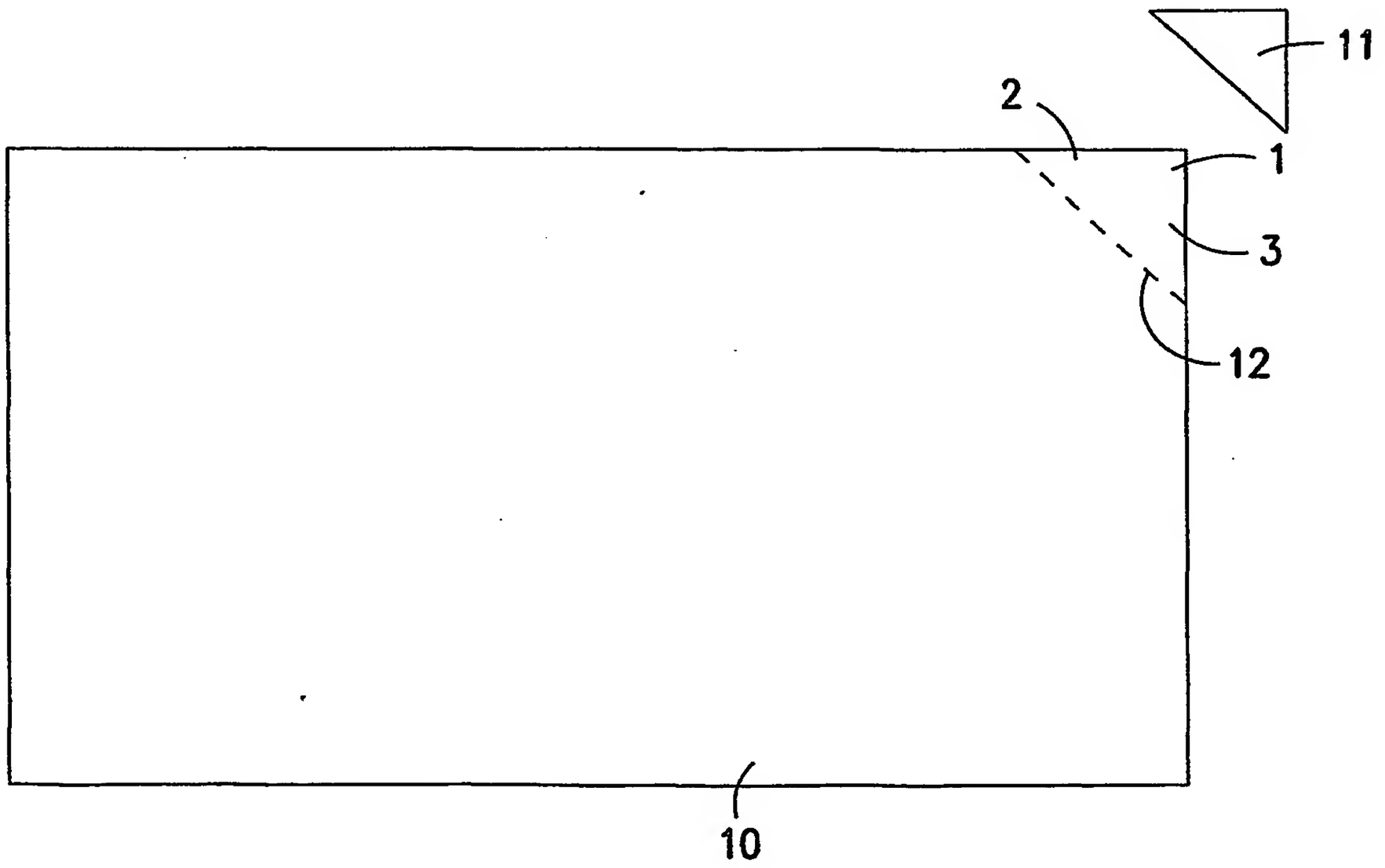

FIG. 6

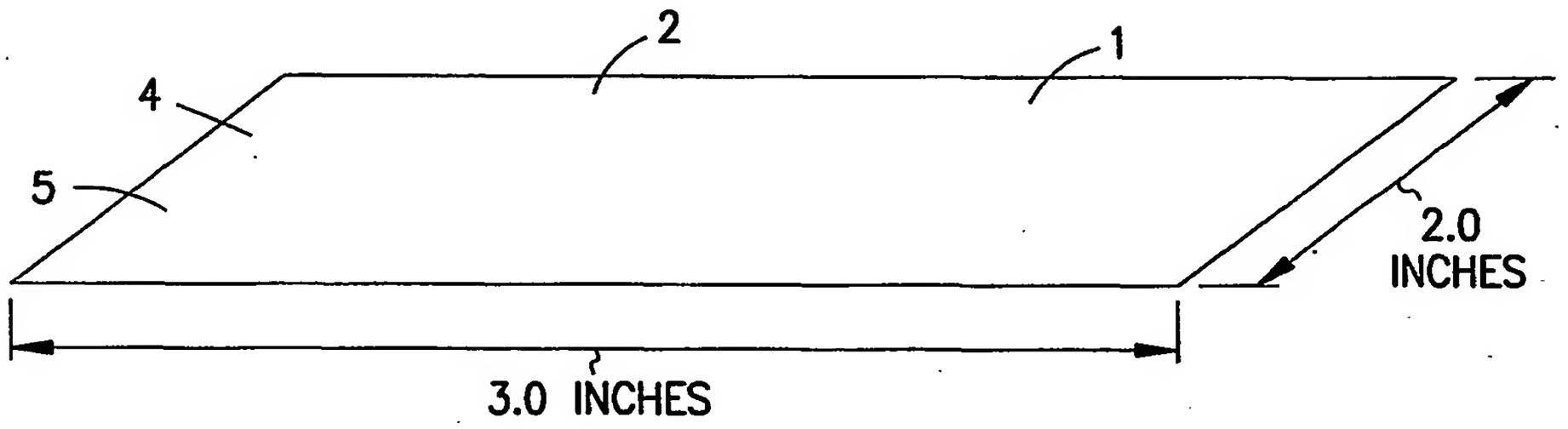

FIG. 7

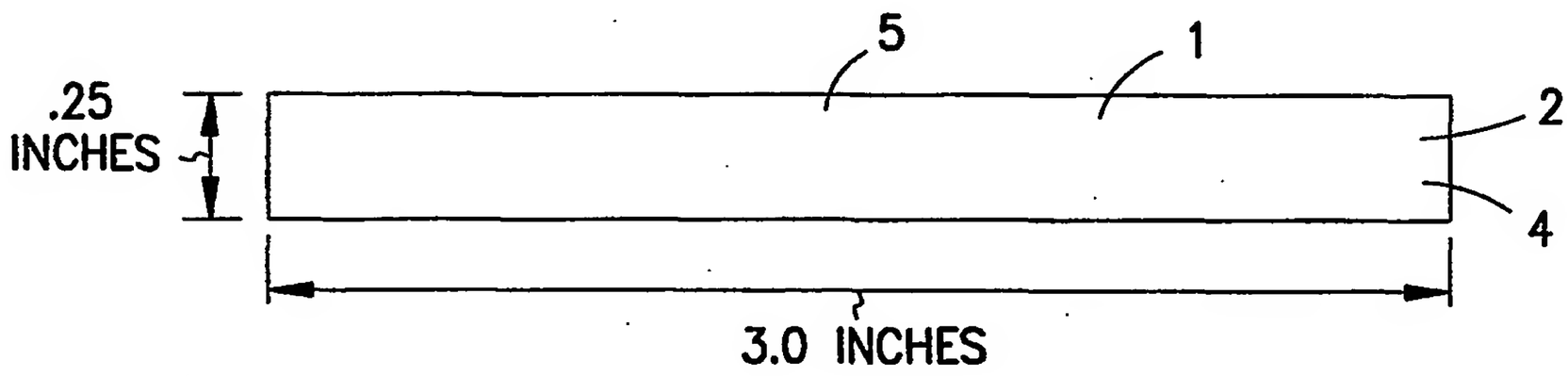

FIG. 8

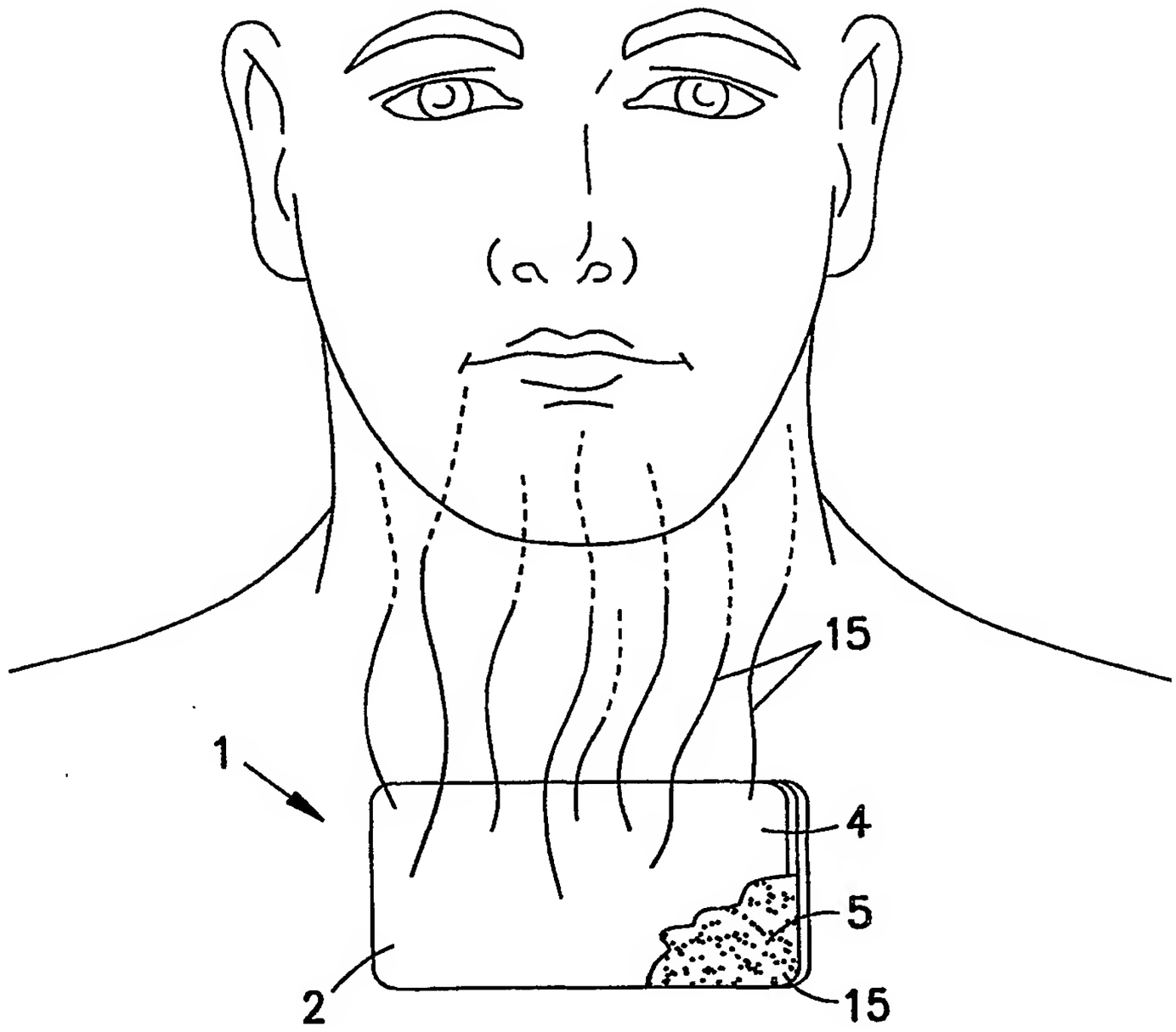

FIG. 9

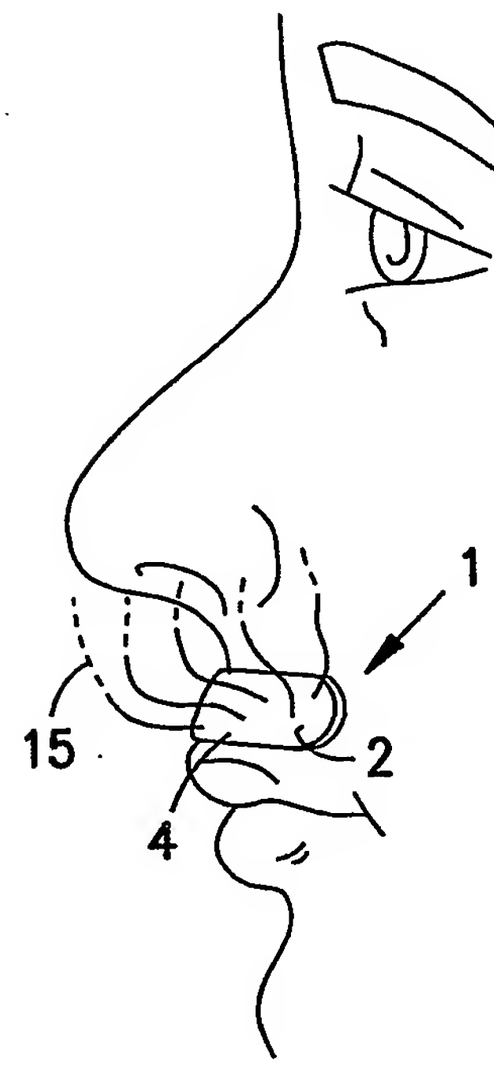

FIG. 10

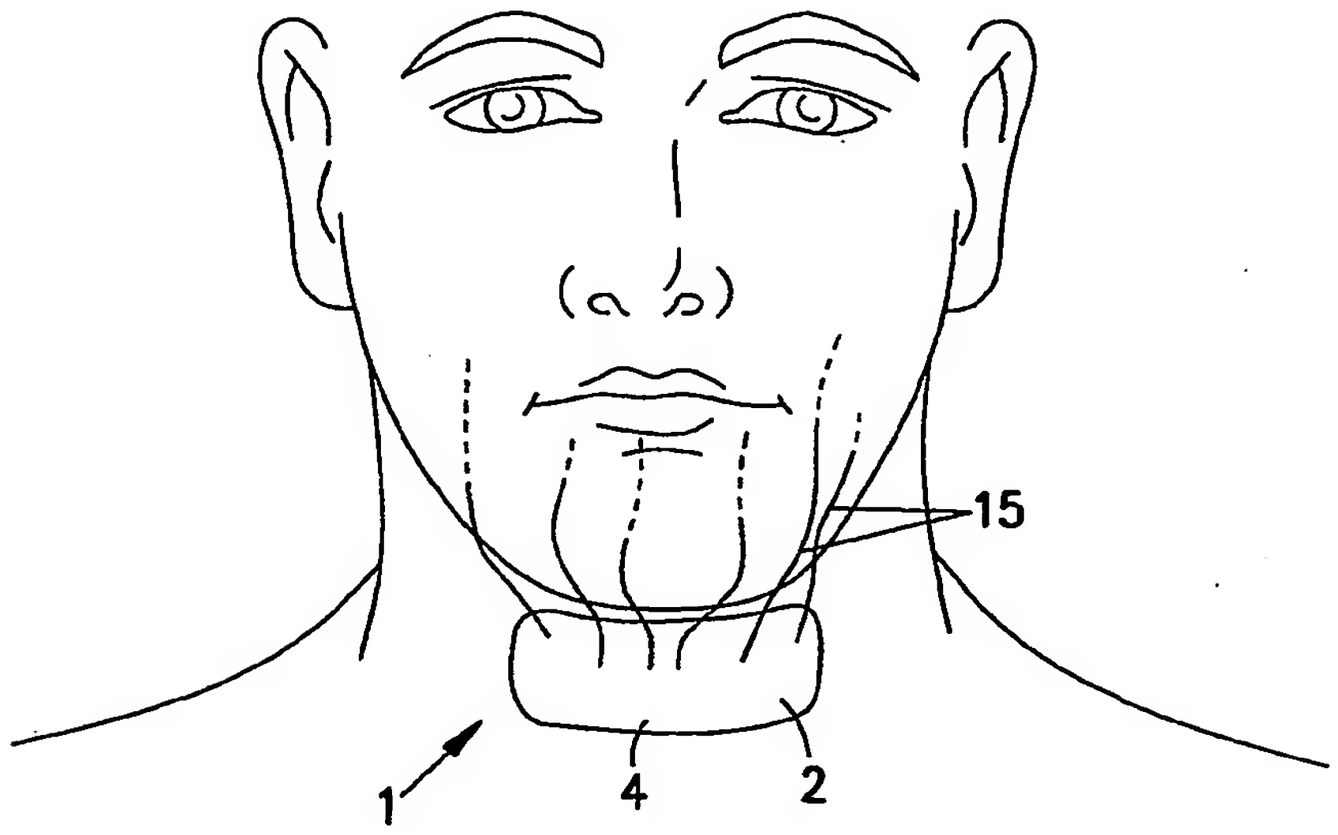

FIG. 11

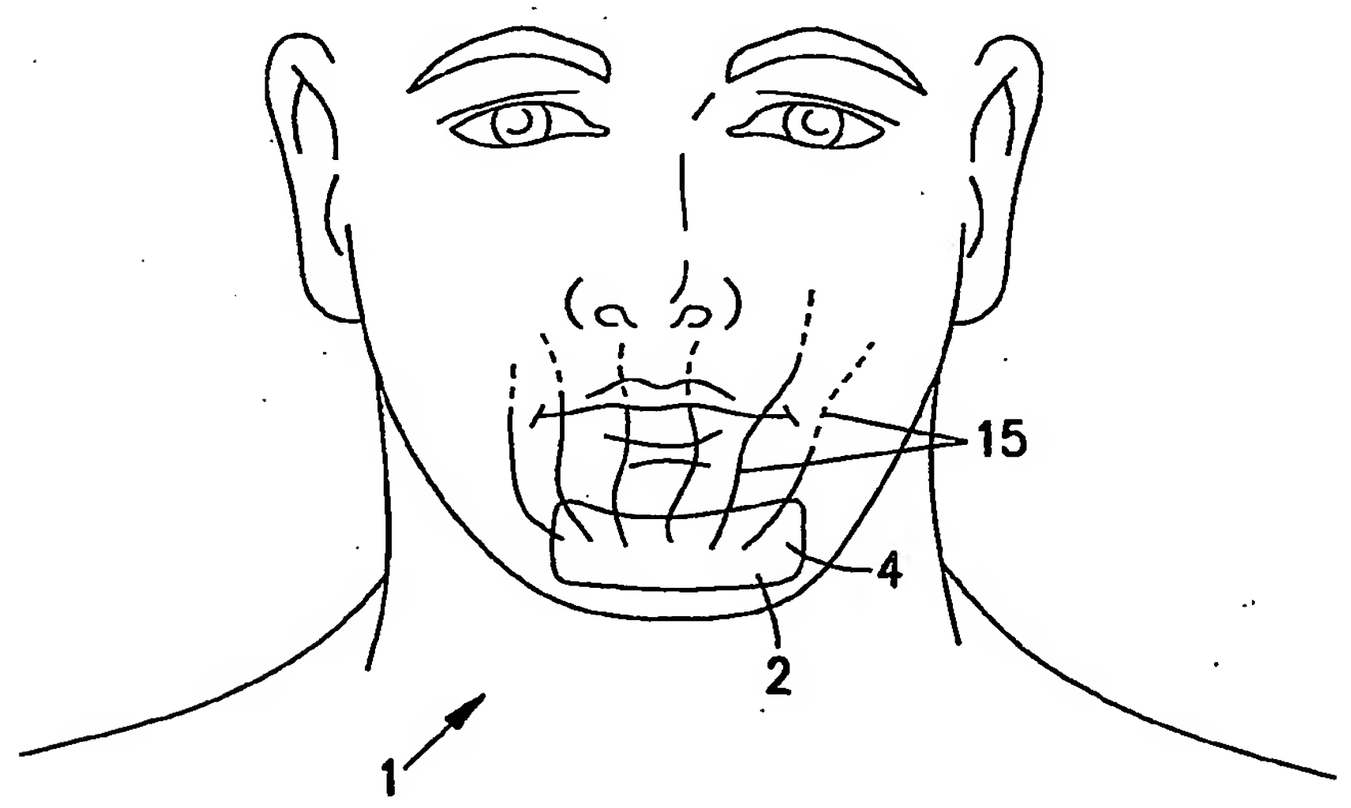

FIG. 12

INTERNATIONAL SEARCH REPORT

Inter al Application No
PCT/US 00/12969

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ, CHEM ABS Data, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E,L	US 6 090 403 A (BLOCK LESLIE L ET AL) 18 July 2000 (2000-07-18) Document throwing doubts on the validity of the priority column 7, line 62 -column 8, line 50	1-14, 20-41, 48-55
X	EP 0 674 913 A (LECTEC CORP) 4 October 1995 (1995-10-04) page 6 -page 8; examples 12,15	1-14, 16-27, 29-41, 43-45, 48-55, 57-59

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 February 2001	09/02/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Boulois, D

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inte I Application No
PCI/US 00/12969

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 750 905 A (KAO CORP) 2 January 1997 (1997-01-02) page 10; table 1	1-3, 7-14,20, 22,27, 29-31, 34-41, 43, 48-55,57
X	US 5 456 745 A (LIST HARALD ET AL) 10 October 1995 (1995-10-10) column 16 -column 17; examples 23,24	1-3, 7-11,13, 14,16, 20,21, 27, 29-39, 41,43, 44, 48-53, 55,57,58
A	WO 93 00115 A (FISCHEL GHODSIAN FARIBA) 7 January 1993 (1993-01-07) the whole document	1-61
A	WO 86 02270 A (BEKE MGTSZ) 24 April 1986 (1986-04-24) the whole document	1-61
A	WO 97 39741 A (NATHANSEN CHRISTINA ;HOECK ULLA (DK); KREILGARD BO (DK); PHARMACIA) 30 October 1997 (1997-10-30) page 19, line 6 - line 9	1-61

INTERNATIONAL SEARCH REPORT

Inter al Application No
PCT/US 00/12969

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